U.S. DEPARTMENT OF COMMERCE
National Technical Information Service

PB-265 417

Incentives for Research and Development in Pest Control Volume I

Arthur D. Little, Inc, Cambridge, Mass

Prepared for

National Bureau of Standards, Washington, D C Experimental Technology Incentives Program

Dec 76

EPA — 540/9-77-008

PB 265 417

INCENTIVES FOR RESEARCH AND DEVELOPMENT IN PEST CONTROL

VOLUME I

DECEMBER 1976

FINAL REPORT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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U. S. DEPARTMENT OF COMMERCE
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National Technical Information Service
Springfield, Virginia 22151

BIBLIOGRAPHIC DATA SHEET

1. Report No. EPA-540/9-77-008

2.

3. Recipient's Accession No.

4. Title and Subtitle
Incentives for Research and Development in Pest Control
Volume I

5. Report Date December 1976

6.

7. Author(s) Alfred E. Wechsler, John E. Harrison, Alan Burg, Donald Gibbons, Joanne Perwak, Robert Terry

8. Performing Organization Rept. No.

9. Performing Organization Name and Address
Arthur D. Little, Inc.

10. Project/Task/Work Unit No.

11. Contract/Grant No. 68-01-3133

12. Sponsoring Organization Name and Address
National Bureau of Standards , Experimental Technology
Incentive Program abd
Environmental Protection Agency, Office of Pesticide Programs,
Strategic Studies Unit, Washington, D.C. 20460

13. Type of Report & Period Covered

14. code 500/01

15. Supplementary Notes
Frederick W. Talcott, Project Officer

16. Abstracts Industry, the principal innovator and developer of pest control methods, feels that existing economic, technical, and regulatory barriers can significantly inhibit the development of new pest control products. The federal government desires to reduce or eliminate these barriers, without compromising its congressionally mandated goals of preventing unreasonable adverse effects of pesticides on humans and the environment. The purpose of this program is to identify, develop, and evaluate incentives (externally applied influences) that the federal government can offer to reduce these barriers and thereby encourage the continued development of pest control methods by industry.

17. Key Words and Document Analysis. 17a. Descriptors

research and development
pesticides
economic incentives
pesticied innovation
history
incentive framework
final incentives
minor use pesticides
integrated pest management
regulatory hindrances to R&D

government support of basic research
information and training for users
lengthen patent life
improved communications
advertise safety on product label
reduce risk of product development

17b. Identifiers/Open-Ended Terms

17c. COSATI Field/Group

18. Availability Statement
1a

19. Security Class (This Report) UNCLASSIFIED

20. Security Class (This Page) UNCLASSIFIED

21. No. of Pages 138

22. Price PCA07 / MF A01

FORM NTIS-35 (REV. 10-73) ENDORSED BY ANSI AND UNESCO. THIS FORM MAY BE REPRODUCED USCOMM-DC 8265-P74

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EPA- 540/9-77-008

Contract 68-01-3133

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ACKNOWLEDGMENTS

This program was conducted by Arthur D. Little, Inc., under EPA Contract 68-01-3133. Dr. Alfred E. Wechsler was the project director, Ms. Joan E. Harrison the assistant project director. Other key participants at Arthur D. Little, Inc., included: Dr. Alan Burg, Ms. Paula Didriksen, Dr. John Funkhouser, Mr. Donald Gibbons, Mr. Robert Ludwig, Dr. Hadi Madjid, Ms. Jane Metzger, Ms. Joanne Perwak, Mr. Michael Michaelis, Mr. Donald Senechal, Mr. Robert Terry, and Ms. Judith Varone. Dr. William Matthews (MIT) was a consultant to the program.

The work was performed under the guidance and with the assistance of Mr. Frederick W. Talcott (project officer) and Dr. Jay Turim of the Office of Pesticide Programs, EPA; and Mr. Dan Fulmer and Mr. Phil Harter (project officers) and Dr. Jordan Lewis of the Experimental Technology Incentives Program, National Bureau of Standards.

The ADL project staff gratefully acknowledges the contribution of representatives of many U.S. pesticide companies whose cooperation and valuable comments and critique made this work possible and meaningful. Similarly, the extensive assistance and cooperation provided by the staffs of EPA, USDA, and many other federal agencies, industry and farm associations, and environmental groups was essential to the program.

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PREFACE

Starting with the most general information and ending with the most specific, this report is organized for those who have an overall interest in the program. Part One presents an overview of the entire program including the results. Part Two presents the detailed results of the program, i.e., the incentives. The Appendices present the details of supporting and background information used in the development of these incentives. Many readers, however, will have one or more specific areas of interest and may wish to read only those related parts of the report. The following topical index is provided to help readers locate the major areas of interest.

The incentives:

An overview of those selected page 43
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An overview of other promising incentives not selected page 45
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Their general reactions to the program page 52
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  - FIFRA Section 3 Registration Requirements page 79
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  - Basic Research page 87
  - OPP/Industry Interactions Page 113
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Proceedings of the Conference on Developing Incentives for Pest Control, which have been published separately,* contain the following:

- Addresses given by representatives of government, industry, and the ADL project team Chapter II*
- Summaries of workshops held for discussion of specific incentives Chapter III*
  - Increase Availability of Minor Use Pesticides
  - Increase Utilization of Integrated Pest Management
  - Decrease Regulatory Hindrances to R&D
  - Increase Government Support of Basic Research
  - Advertise Safety on Product Label
  - Reduce the Risk of Product Development by Industry

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*"Developing Incentives for Pest Control Methods." Proceedings of a Conference. Arthur D. Little, Inc., under Contract 68-01-3133 to Office of Pesticide Programs, U.S. Environmental Protection Agency and Experimental Technology Incentives Program, National Bureau of Standards, 1976.

Conference recommendations concerning general actions to be taken by EPA and specific actions with regard to certain incentiees	Chapter IV*
Reactions of conference attendees	Chapter V*
Conference Program	Appendix A*
List of Participants	Appendix B*

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[*] "Developing Incentives for Pest Control Methods." Proceedings of a Conference. Arthur D. Little, Inc., under Contract 68-01-3133 to Office of Pesticide Programs, U.S. Environmental Protection Agency and Experimental Technology Incentives Program, National Bureau of Standards, 1976.

PART ONE

PROGRAM OVERVIEW AND RESULTS

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I. PROGRAM SUMMARY

PURPOSE

National goals of ensuring an adequate supply of food, feed, and fiber, and of disease prevention and control, have benefited greatly from the development, production, and use of pest control methods. Equally important goals of human and environmental health and safety may be adversely affected by the same development. For over thirty years, various agencies of the federal government have attempted to achieve an appropriate balance of these considerations through pesticide regulation.

Industry, the principal innovator and developer of pest control methods, feels that existing economic, technical, and regulatory barriers can significantly inhibit the development of new pest control products. The federal government desires to reduce or eliminate these barriers, without compromising its congressionally mandated goals of preventing unreasonable adverse effects of pesticides on humans and the environment. The purpose of this program is to identify, develop, and evaluate incentives (externally applied influences) that the federal government can offer to reduce these barriers and thereby encourage the continued development of pest control methods by industry.

APPROACH

The work was organized into two major tasks. First, the history of pest control innovation was analyzed and influences on current decision-making concerning industrial pesticide R&D were studied to provide background for the development of incentives. For the second task, 64 preliminary incentive ideas were devised and evaluated in accordance with a conceptual framework. These incentives were screened and ranked according to their feasibility, the acceptance by parties at interest in their implementation, and their potential contribution to realizing the objectives of this program. Nine particularly promising incentives were developed further and evaluated in several possible future scenarios. The insights and comments of representatives of the pesticide industry and government staff concerned with pesticide development and regulation were sought at several stages in the development of incentives.

RESULTS

Recommended Incentives

The following incentives* are recommended for implementation by the government as soon as possible.

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*Incentives are listed by number as identified in Section IV and Part Two of this report. They reflect ADL staff views and other inputs received throughout the program. The incentives are generally consistent with those recommended for implementation in the Workshop on Developing Incentives for Pest Control Methods.

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#3 Decrease Regulatory Hindrances to R&D

- Give serious consideration to self-certification of efficacy by applicants
- Give recognition to the need for a fixed set of data requirements at the time of initial submission for registration
- Give serious consideration to limited marketing under provisional/conditional registration
- Issue Section 3 guidelines as soon as possible and specify procedures for updating the guidelines which will reinforce their stability, yet permit flexibility
- Continue opportunities for top level EPA-industry discussions
- Provide an information package for new registrants
- Add resources to EPA in the area of non-agricultural pest control
- Provide a weekly or monthly progress report with broad distribution concerning the status of regulatory activities
- Prepare a public statement relative to the current "log jam" in the registration/reregistration process indicating, in practical terms, the problems, interim policy and procedures, anticipated long-term policy and procedures, and realistic schedules for the registration/reregistration processes

#9 Reduce the Risk of Product Development by Industry

- Continue to develop and implement a stable regulatory plan which addresses timely solution of administrative, legal, and political as well as scientific issues
- Develop a commitment to top level EPA/industry communications and mutual effort to resolve critical regulatory problems
- Develop and support a stable philosophy and policy for pesticide regulation based upon scientific understanding and effective risk/benefit analysis
- Devote efforts to developing specific stable criteria for pesticide registration, adverse effects and benefits of pesticides
- Work with industry and other groups to resolve critical issues such as data validation, carcinogenicity policy, 3(c)(1)(D), etc.

#1 Increase the Availability of Minor Use Pesticides

- Clarify policies on minor use registration

- Implement self-certification of efficacy for minor use products

- Develop and implement a crop grouping plan

- Encourage and participate in joint EPA/USDA/State efforts in minor use pesticide planning and registration

- Integrate the activity of user groups, state government organizations and IR-4 at the state level

- Establish a full-time staff at USDA as a focus for minor use activities

In addition, the following incentives are expected to have less cceptance and impact but should nevertheless be considered for future mplementation.

#6 Lengthen Patent Life

- Support industry efforts to lengthen the patent life of proprietary pesticides by compensating for the time required for the registration process

#8 Advertise Safety on Product Label

- Implement changes in pesticide labeling practice, which help to differentiate between the least hazardous pesticide products (to humans) and others

#2 Increase Utilization of Integrated Pest Management (IPM)

Encourage the use of IPM where economical and effective in meeting user needs through the following mechanisms:

- Increase federal funding for pilot programs

- Communicate results of pilot programs to potential users through advertising, seminars, and/or training programs

- Conduct research on economic threshold levels of pesticide use

- Determine attitudinal barriers, and potential solutions, to use of IPM

- Use pilot programs of limited duration and with specific objectives as a mechanism for introducing more sophisticated methods of IPM developed cooperatively by scientists and economists.

#5 Increase Information and Training for Pesticide Users

EPA and USDA fund a program of expanded information and training services in all areas of pest management

In order to proceed with these incentives, EPA and OPP policy makers and staff (beginning at the highest level within the agency) should initiate a sustained commitment to meaningful effective participation with industry in addressing and solving mutual problems of pesticide registration and regulation. EPA should identify the senior individual(s) within OPP responsible for interacting with industry. These individuals should be given responsibility and authority to implement incentives and other changes which result from this interaction.

As a next step, EPA should convene working conferences on specific incentives and issues where pesticide user, industry and other federal agency inputs are essential. EPA and other federal agencies should guarantee the attendance by top level decisionmakers and commitment to implementation of mutually acceptable actions developed in these meetings. Industry should respond by providing appropriate top level staff and commitment to resolve important issues.

Present Outlook for Incentives

During the development of incentives, several issues arose that remain unresolved:

Should and can EPA act as a promoter, as well as a regulator, of pesticides?

Which federal agencies should sponsor incentives--EPA because of its regulatory role or another agency with a perhaps more direct interest in the problems to be addressed?

Issues such as these and others identified in this program must be addressed by both industry and the government, and their resolution will influence not only which incentives are selected for implementation but also in what way they are implemented.

In spite of these uncertainties, the present outlook for nine incentives examined in the program has been evaluated and is summarized in Table 1, which rates the incentives in terms of major determinants of the success: the feasibility, i.e., the ease of implementation and the cost, and the importance and the likelihood of acceptance by the three major parties at interest. Although none of the incentives satisfies all requirements and all viewpoints, they all appear to offer some chance for success.

Future Outlook for Incentives

Consideration of the incentives from a futures viewpoint led to the following conclusions:

TABLE 1

CURRENT OUTLOOK FOR INCENTIVE ACTIONS

	POTENTIAL IMPORTANCE OF PROBLEM AREA			POTENTIAL ACCEPTANCE OF INCENTIVE			POTENTIAL FEASIBILITY OF INCENTIVE	
INCENTIVE/PROBLEM AREAS	Industry	Government	Pesticide User	Industry	Government	Pesticide User	Difficulty in Implementation	Anticipated Cost
1. Increase Availability of Minor Use Pesticides	Low	Moderate	High	Moderate	Moderate	High	Moderate	Moderate
2. Increase Utilization of Integrated Pest Mangement	Low	Moderate	Moderate	Low	High	Moderate	Low	Moderate
3. Decrease Regulatory Hindrances to R&D	High	Moderate	Moderate	High	Moderate	Moderate	Moderate	Low
4. Increase Government Support of Basic Research	Low	Low	Low	Moderate	Moderate	Low	Moderate	Moderate
5. Increase Information and Training for Users	Low	Moderate	Moderate	Low	Moderate	High	Low	Moderate
6. Lengthen Patent Life	High	Low	Low	High	Low	Low	High	Low
7. Improve Communication Between Pesticide Industry and EPA	Moderate	Moderate	Low	Moderate	Moderate	Moderate	Low	Low
8. Advertise Safety on Product Label	Low	Low	Moderate	Moderate	Moderate	High	Moderate	Low
9. Reduce the Risk of Product Development by Industry	High	Low	Moderate	High	Moderate	Moderate	Moderate	Moderate

- Examination of several incentives in the context of possible future scenarios for the years 1980, 1990, and 2000 suggests that no single set of incentives will be appropriate.

- While the success of some incentives depends in large part on the realization of particular future scenarios, the success of others is future independent. Incentives involving registration changes are the least dependent on specific future scenarios.

- Incentives promising short-term results will be the most accepted by the parties at interest. Any long-term incentives for pesticide R&D will achieve less acceptance in scenarios that include rapid or major societal changes.

- The potential for acceptance and impact of incentives is "mixed" at present, but is greater now than it will be in the future.

Reactions of the Program Participants

Reactions to the incentive program, the need for incentives, and specific incentives have run the gamut from strong opposition or disinterest to enthusiasm. Most negative reactions stem from resistance to any form of government intervention, however well-intended, and from a disbelief in the feasibility of EPA achieving its diverse goals of balancing the costs and benefits of pesticide use. Positive reactions arose from the viewpoint that certain incentive actions, properly implemented, can solve specific problems and from the sincere desire of many industry and government groups to resolve the issues of the pesticide conflict for the public benefit.

CONCLUSIONS

Based upon the results obtained in this program, several conclusions can be drawn concerning the concept and feasibility of providing federal incentives for R&D of pest control methods by industry.

1. Although government and university research led to many early innovations in pest control, private industry is the major force in pesticide development today. Thus factors that once brought about major advance are no longer important, replaced by market pressures and opportunities, the competitive nature of the agricultural chemical industry, and modern synthesis, analysis, and screening technology. Therefore, incentives have to influence these newer forces on pesticide R&D.

2. No single major incentive action can directly stimulate innovation in pest control; rather a multiplicity of factors and incentive actions by both industry and government must be combined before increasingly innovative, safe, effective, and economical pesticides can be developed. Short-term incentives are likely to be more easily accepted and implemented, can demonstrate success of the incentive process, but may ultimately have only modest impacts on the R&D process. Long-term ncentives may be difficult to implement because of the federal

bureaucratic process, will require long, sustained, and probably expensive efforts, but could have greater impact on R&D over time.

3. The problem areas to which incentives could be addressed are inherently complex. Without the close support, guidance, and real interest of both the federal government, as incentive provider, and industry, as incentive recipient, identification and evaluation of incentives is difficult at best, and effective implementation would be impossible.

4. Pesticide regulation is but one area for change. By themselves, changes in regulations cannot ensure that the goals of industrial development of innovative pesticides will be reached. Equally important are changes in the attitudes and working relationships of the parties involved. The acceptance and recognition of each other's position, the openness and frequency of information exchange, and mutual respect for the competence and reasonableness of the individuals involved are the key to successful solution of common problems.

5. The process of developing a consensus on desired incentives among the parties involved is tedious and time-consuming. Similarly, consensus concerning proper implementation approaches to these incentives will be difficult to achieve. Nevertheless, areas of agreement which show promise of real beneficial impact to all parties can be found and the projected benefits will be worth the effort.

6. The success of this and similar incentive programs, and other programs sponsored by ETIP on government encouragement of technological change depends upon firm commitment of the sponsors to implement recommendations. Lack of commitment undermines current efforts to establish the needed trust and confidence between government and industry.

II. INTRODUCTION

A. THE INCENTIVE PROGRAM AND ITS OBJECTIVES

The consequences of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, as amended in 1972), and its implementation in the following years, are just now becoming apparent. It is in response to these consequences that this incentive program was initiated. The program is based on the assumption that further action may be necessary to deal with some of the consequences of regulation. The challenge of this program has been to identify federal government actions that address problems arising from FIFRA, as amended, without compromising the original objectives of the legislation. Conversely, an additional objective of this program has been to identify actions that further the original objectives of FIFRA, as amended, but do so in a way that does not aggravate the problems already caused by previous implementation actions.

The identification of problems caused by regulations is difficult because of the multiplicity of factors involved in the areas of potential impact. For example, the development of new pesticides, the vitality of the pesticide industry, and the availability of pesticides to the user are all areas of potential impact, controlled and influenced by many factors other than regulatory actions. It is difficult, if not impossible, to isolate and measure the specific effects of regulations in broad areas such as these.

More specific and direct effects, however, can be attributed to regulations. For instance, an increase in the time and cost of pesticide discovery and development has resulted from the testing and administrative requirements for product registration. This has had the effect of making companies less willing to register products for market areas offering a small return, i.e., for so-called minor uses. This in turn has led to a shortage of available registered products that can be used for these pest situations.

The most widely discussed impact of FIFRA, as amended, and its implementation is an expected long-term decrease in the productivity of R&D efforts of pesticide companies, primarily because of the diversion of R&D funds from product development to product registration. No such decrease is yet apparent (see Appendix B), however; because of the lag time involved between the discovery and commercialization of a pesticide (5 to 7 years), another 5 to 10 years may be necessary before any reliable trends in R&D productivity are indicated.

B. IDENTIFICATION OF INCENTIVES

A variety of possible incentives were explored and screened according to a number of criteria (the incentives and criteria are presented in detail later in this report). The following discussion briefly presents some of the general criteria used in the screening.

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1. The actions had to act as incentives, i.e., stimulate desired change, providing not only a solution to the problem at hand, but hopefully also progress toward further desirable activity. Incentive actions were sought which would eliminate barriers, thereby allowing existing pesticide interests to bring about a desired result. This requirement emphasized those activities--e.g., funding or regulatory actions--that would stimulate the initiative of manufacturers, user groups, and other parties at interest.

2. The incentive actions had to be feasible: i.e., acceptable to those persons or groups whose participation was required for their implementation. Through consultation with many of these groups, this feasibility requirement was used to eliminate grandiose schemes and bold new approaches. It instead focused attention on small changes necessary for acceptable solutions to specific problems.

3. The incentive actions had to meet one of the objectives of this program without negating or interfering with the benefits of other actions designed to meet other objectives. This requirement screened out those actions that compromised the goals of FIFRA, as amended, even though the actions may have been helpful in eliminating some of the identified regulatory problems. It also eliminated actions that could be expected to create additional regulatory problems or aggravate ones that already exist.

Most of the incentive actions considered in this program deal directly or indirectly with pesticide R&D. The innovative activity inherent in pesticide R&D was the focus of this program for several reasons: (1) pesticide innovation has the potential for satisfying several, sometimes opposing, objectives, such as ensuring the continued availability of pest control methods, decreasing the adverse effects caused by pesticide use, and maintaining a vital pesticide industry. (2) As mentioned above, the effect of regulations on pesticide innovation has been a subject of concern to many groups and a decrease in innovative activity is seen by some as a consequence of FIFRA, as amended. (3) Removing barriers to innovation has the potential for long-term, continuing, and desirable effects.

C. THE PROGRAM PARTICIPANTS

A primary activity in this program was communication among the parties at interest, i.e., presenting the ideas developed in this program to those who would be involved in their implementation, obtaining their reaction, and revising the ideas, etc. This report represents a continuation of this activity, presenting a smaller number of more developed ideas to an even wider group of participants. In a sense, the reader of this report is a participant in this program, since hopefully the reactions of the readers will become a source of still further refinement of the proposed incentives.

The initiation of this program came from the Experimental Technology Incentives Program (ETIP), sponsored by the National Bureau of Standards of the Department of Commerce. ETIP desires to stimulate technological change by encouraging the private sector to produce and disseminate new technologies. The ETIP Program seeks to explore ways of identifying and reducing barriers that prohibit the private sector from producing innovations that can help solve the nation's social and economic problems. The ETIP Program also seeks ways to stimulate civilian research and development and to simplify and manage more effectively the government's role in the process of research, of development, and of innovation.

ETIP has conducted a series of experiments with other federal agencies, to help these agencies meet their current objectives while bearing in mind the overall ETIP goals. ETIP presented EPA with the opportunity to collaborate with one of these experiments, and they have participated in the funding, defining, and monitoring of this program.

The Office of Pesticide Programs, which is the branch of EPA that is implementing FIFRA, as amended, assumed the primary role in the development and monitoring of this program. The primary objective of the Office of Pesticide Programs (OPP) is to regulate the availability and use of pesticides on the basis of risk/benefit balancing. As discussed in the preliminary draft of the five-year strategy document prepared by OPP for the implementation of FIFRA, as amended, OPP regulates "availability," allowing on the market only those pesticides that are safe and effective when used as directed. In regulating "use," OPP promotes good application techniques and limits access to the more hazardous pesticide products. In total these efforts attempt to maximize the benefits of pesticides, while minimizing the risks inherent in their use.

OPP recognized the opportunity that this program presented to further their objectives, while at the same time responding to the consequences of previous implementation actions. Throughout the program, OPP expressed interest not only in helping to develop incentives, but also in taking responsibility for implementation of those incentives directly related to its program activities.

Other program participants included representatives from a range of pesticide developers and manufacturers, user groups, government agencies, and environmental groups. These individuals, about 50 in all, suggested ideas for incentive actions, screened and evaluated those actions considered throughout the program, and helped refine those that were finally developed as incentives and are presented in this report.

D. BACKGROUND INFORMATION

(1) The Regulatory Environment

The first federal regulation of pest control agents was the Insecticide Act of 1910, which disallowed fraudulent efficacy claims and authorized the government to seize or ban compounds dangerous to health.

In 1947, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was passed, preventing the interstate distribution or sale of pest control methods that had not been shown to be safe when used as directed and effective for the purpose claimed on the label. Residues remaining on food after use could not exceed the safe tolerance level established by the Food and Drug Administration. A series of amendments passed in 1959, 1961, and 1964 significantly increased the test requirements and the clearance procedures.

In 1970, environmental considerations were emphasized in pesticide regulation through PR Notice 70-15, which provided guidelines for environmental studies required as part of pesticide registration. In December 1970, the administration of FIFRA was transferred to the Environmental Protection Agency, along with the authority to establish tolerance levels for pesticides and their residues in food and food products.

Intensified concern with the condition of the physical environment, increasing public concern about the longer-term health and ecological effects of chemical pesticides, and continuing wide public discussion of the adequacy of pesticide regulatory procedures were among the reasons for passage of the Federal Environmental Pesticide Control Act (FEPCA or FIFRA, as amended)* in October 1972. FIFRA, as amended, added to the existing concerns about human safety and product efficacy a broad consideration of environmental health and safety in the production and use of pesticides. A major goal of FIFRA, as amended, was to prevent unreasonable adverse effects on the environment, taking into account the economic, social, and environmental costs and benefits of pesticide use.

FIFRA, as amended, has set the stage for EPA to develop and promulgate detailed regulations, guidelines, and procedures on pesticide registration and use; for the administrative and judicial processes of pesticide registration, classification, cancellation, and suspension; for EPA internal procedures to implement the law and regulations; and for the conduct of government-sponsored research on pesticides and their regulation.

The purposes and status of some of the sections of FIFRA, as amended, and regulations promulgated therefrom which may have a major impact on the development of pesticide products by industry are summarized in Table 2.

(2) The Pesticide Research and Development Environment

Historically, the circumstances that have surrounded major technical advances in pesticide development innovations have been highly variable; they have involved concentrated research effort, luck, one-man promotional efforts, and, sometimes, serendipity. However, at the time of innovation

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* Throughout this report, this legislation is referred to as "FIFRA, as amended."

TABLE 2

PURPOSE AND STATUS OF SELECTED SECTIONS OF FIFRA, AS AMENDED, AND REGULATIONS

Section (Regulation)	Purposes	Status
3 Registration of Pesticides	Establish requirements, exemptions, procedures, and classification of pesticides for registration	
40 CFR 162.40-162.96	Provide guidelines for registering pesticides	Final regulations issued
3(c)(1)(D)	Provide for compensation for use of data previously submitted	Special policy statement issued; regulations forthcoming
4 Restricted Use Pesticides, Certified Applicators	Provide for a procedure for certification of applicator of pesticides	Final regulations issued
5 Experimental Use Permits	Provide for an experimental use permit for a pesticide	Final regulations issued
6 Administrative Review	Provide for cancellation, change in classification, suspension and public hearings and review of pesticides	"Rules of Practice" finalized
10 Protection of Trade Secrets and Other Information	Maintain confidentiality of trade secrets, commercial and financial information	"Internal opinion" issued by Office of General Counsel
12 Unlawful Acts (a)(2)(G) Use inconsistent with label	Prevent the use of pesticides in a manner inconsistent with the label	Pesticide Enforcement Policy Statements issued--no regulations to be issued
15 Indemnities	Provide indemnity payments to persons suffering losses resulting from specific cases of suspension and cancellation of pesticides to prevent imminent hazards	No regulations to be issued

TABLE 2 (Continued)

Section (Regulation)	Purposes	Status
19 Disposal and Transportation	Provide for procedures and regulations for disposal and storage of pesticides and containers	Final regulations issued
20 Research and Monitoring	Provide for research necessary to carry out purposes of FIFRA, as amended, giving priority to research to develop biologically integrated alternatives for pest control	No regulations to be issued
24 Authority of States	Permit states to register pesticides for use within a state for special local needs	Regulations proposed

three favorable circumstances have usually been present:

- A demand existed for a result produced by a pest control product.
- The required technology was available and its application was recognized.
- Time and money to invest were available.

Demand for pesticides, as for all products, depends on the existence of an unfilled need. However, it is important to recognize that the need must be perceived as not being met by an existing pest control methods. The perception that existing products satisfy needs has significantly hindered the development of new products. As one example, innovative activity in biological insect control dropped sharply at the onset of chemical controls.* As another example, at least one company stopped screening chemicals for insecticidal activity in the late 1950's because of the assumption that nothing could be cheaper, more effective, and cover a wider spectrum than DDT.**

A basic ingredient in innovation is the scientific and technical capability that allows the innovation to occur in the first place. Prior to World War II, chemical control was severely limited by the lack of technical capability for synthesizing large quantities of organic materials cheaply. The effort necessary to develop this capability was stimulated by the exigencies of the war. Chemical controls now are commonplace. Biological controls, however, are still limited, because our knowledge of natural control mechanisms, on which these controls are based, is still too skimpy to permit commercial manufacture of such products cost-effectively.

Before an innovation can be successful, some mechanism must exist through which the demand for the pest control method, the technology to produce it, and the resources to produce the pest control methods can be connected. This mechanism necessarily involves money and time, both of which can come from government, private non-profit institutions (e.g., universities), or private profit-making institutions. Aside from some private commercialization of a few inorganic compounds, in the first half of this century, most of the discovery, and much of the production and distribution of pest control methods, was done by the federal government. Government involvement climaxed from 1940-1945 to meet World War II pest control needs.

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* Around 1950 some government researchers heavily involved in biological control research were directed to stop that activity and begin work on determining the correct application techniques for chemical controls. Chemical insect controls appeared to be the final answer in insect control.

** Both biological control research and insecticidal screening in this company were stimulated by the environmental outcry against DDT in the early 1960's. Only long-term unmet needs are significant "pulls" on innovation: short-term needs like epidemics or foreign-pest outbreaks are responded to by screening and "making do" with existing products.

After World War II, industry accepted the challenge of developing and marketing pesticides on a large scale. This is a complex process involving chemical or biological synthesis, screening, laboratory and field studies, market research, production research, etc., the results of which must be carefully evaluated and integrated before an economically viable product is ultimately developed. The process of development is long, costly, and subject to risks and uncertainties not under the direct control of the developer. Currently, government organizations and universities contribute to basic research, understanding of pest physiology, pesticide application and pest control methods, but do not alone have the resources to bring the pesticide development process to successful completion.

More detailed background information is presented in Appendices A and B.

III. APPROACH

Figure 1 represents schematically the approach taken in the conduct of this program.

A. TASK I--BACKGROUND STUDIES

The purpose of Task I was to set the stage for the development of incentives. Specifically, a major goal was to determine the problems that should be addressed by incentives and some of the parties involved and circumstances surrounding these problems.

Initially, the work focused on innovation in pest control and potential problems in future pesticide development. The history of pesticide development from 1900 to the present was examined through a review of literature and by interviews with persons who had been involved in the discovery and development of pesticides. This historical information was analyzed from several perspectives:

(1) Periods of particularly intense innovative activity were identified (primarily 1940-1945 and the late 1950's). The circumstances surrounding innovations--such as the funding sources, state of technology, and nature of pest control demand--were examined in order to determine the most important influences.

(2) Potentially important factors such as pest epidemics, state and federal regulations, and increases or decreases in government funding were examined in order to identify any apparent effect of such factors on pesticide innovative activity.

(3) Several specific case examples of pesticide innovation were examined in order to identify the events that have occasioned the innovations.

The results of this effort (see Section IV-A and Appendix A) suggested that the factors relevant to pesticide innovation and development are complex, unique to particular situations and, in general, not repeatable. Thus, the work focus was changed to emphasize present day innovation activities and the influences on decision-making concerning them. Because almost all pesticide innovation in the last 15 years has taken place in the commercial sector, representatives of 12 carefully selected small and large companies actively conducting R&D were interviewed by project staff. In most cases, interviews were conducted by staff members from ADL with from two or three representatives of the company, usually including the director of R&D. These interviews were directed at determining the factors that influenced successful R&D, for example:

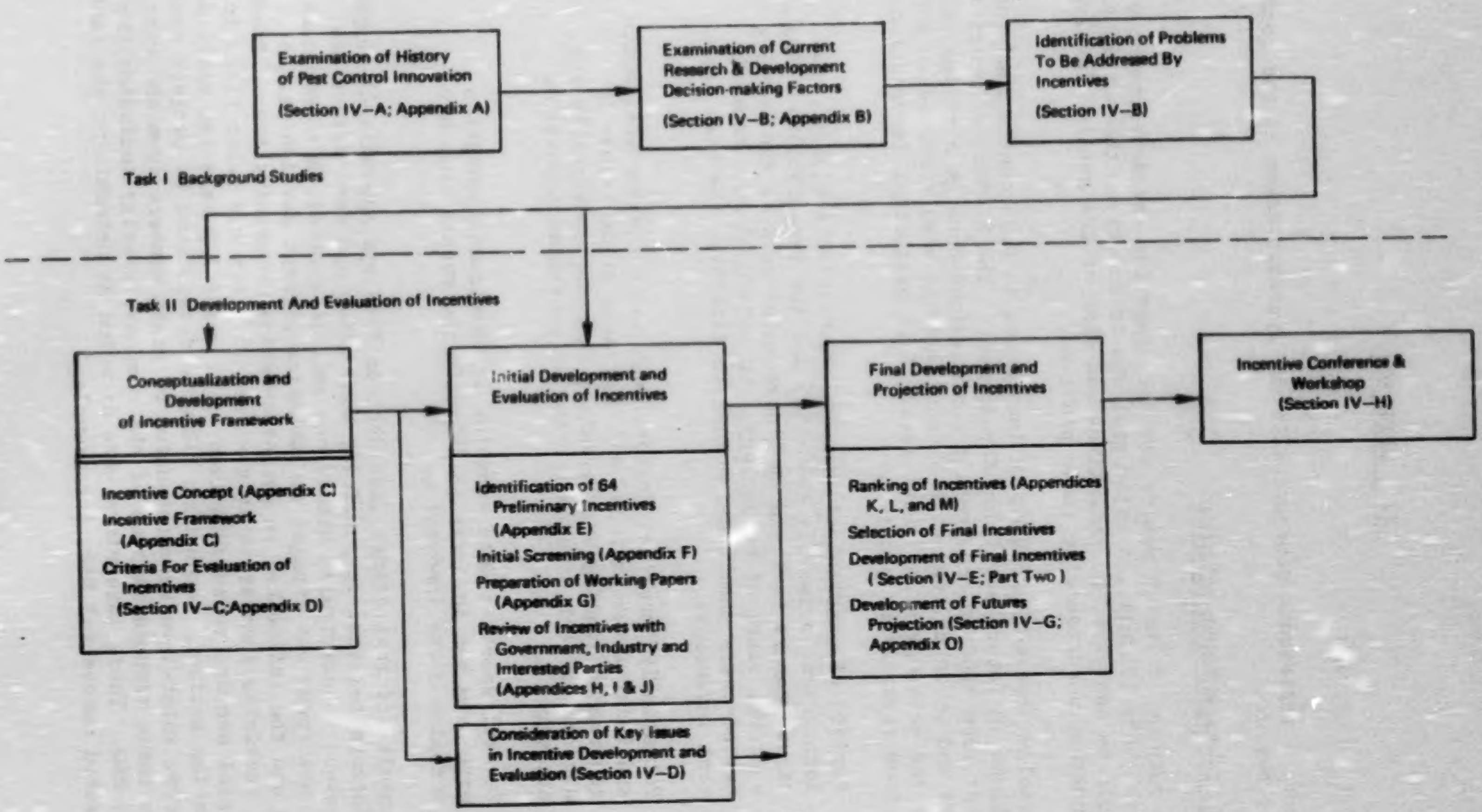
Examination of History of Pest Control Innovation
(Section IV–A; Appendix A)
Examination of Current Research & Development Decision-making Factors
(Section IV–B; Appendix B)
Identification of Problems To Be Addressed By Incentives
(Section IV–B)
Task I Background Studies
Task II Development And Evaluation of Incentives
Conceptualization and Development of Incentive Framework
Incentive Concept (Appendix C)
Incentive Framework (Appendix C)
Criteria For Evaluation of Incentives (Section IV–C;Appendix D)
Initial Development and Evaluation of Incentives
Identification of 64 Preliminary Incentives (Appendix E)
Initial Screening (Appendix F)
Preparation of Working Papers (Appendix G)
Review of Incentives with Government, Industry and Interested Parties (Appendices H, I & J)
Consideration of Key Issues in Incentive Development and Evaluation (Section IV–D)
Final Development and Projection of Incentives
Ranking of Incentives (Appendices K, L, and M)
Selection of Final Incentives
Development of Final Incentives (Section IV–E; Part Two)
Development of Futures Projection (Section IV–G; Appendix O)
Incentive Conference & Workshop (Section IV–H)

FIGURE 1 APPROACH TAKEN IN THE DEVELOPMENT AND EVALUATION OF INCENTIVES FOR PESTICIDE R&D

(1) The factors that "make or break" a pesticide in each stage of development, i.e., which influence the corporate decision to go pursue further development of the product.

(2) The factors that could be modified by external influences and that, therefore, might be suitable for government incentives.

(3) Specific barriers caused by regulatory activities and other external factors.

After each interview, the results of the discussion were summarized and circulated among ADL team members for their review. A list of factors of importance in pesticide R&D was assembled and sent for review to representative companies at which interviews had been conducted (see Section IV-B and Appendix B).

On the basis of the background material on pesticide innovation, interviews with industry, the identification of the factors of importance to pesticide R&D and through discussions among ADL and EPA staff, problem areas that could be addressed by incentives were identified. A significant effort was devoted to relating the divergent and somewhat opposing goals of EPA to problems that could be addressed most effectively by incentives. As a result, the multi-objective nature of the program evolved and the challenge of meeting divergent goals through incentive actions was identified.

B. TASK II--DEVELOPMENT AND EVALUATION OF INCENTIVES

This task was conducted in three phases:

- Conceptualization and Development of an Incentive Framework;
- Initial Development and Evaluation of Incentives; and
- Final Development, Evaluation, and Projection of Incentives.

ADL staff members with different backgrounds and expertise contributed to each phase of the program. The core team consisted of nine staff members experienced in biology and chemistry, pesticide regulation, agricultural economics, public administration and political science, pesticide research and development, pesticide industry and economics, and innovation and incentives. Members were chosen to represent different skills and interests of the parties concerned with the incentive program.

(1) Conceptualization and Development of an Incentive Framework

A first step in the process of incentive development was the creation of a "theoretical framework" (see Appendix C). It was "theoretical" in the sense that several assumptions were made:

- The goals and objectives of various parties could be clearly specified;

- The problems affecting these parties were relatively independent of each other and could be identified and categorized;

- The actions that would aid in the solution of these problems could be defined easily;

- The providers and the recipients of the incentives could be clearly delineated; and

- The evaluation could follow a straightforward process in which the incentive providers and recipients would be the principal groups determining the acceptability, feasibility and effectiveness of the incentive action.

As work progressed, these assumptions were not entirely validated. First, difficulties were encountered in defining specific goals and objectives of OPP, agriculture, ETIP, and industry with regard to pesticides and the incentive program, and in resolving the major conflicts among these goals and objectives. Furthermore the problems of pesticide research and development caused by regulation are complex and interrelated. Finally, the ultimate feasibility of the individual actions taken may depend upon the reactions of many parties--agriculture, industry, the public, Congress, OPP, other federal agencies, public interest groups--and not just those of the specific incentive provider or recipient.

Therefore, effort was devoted to developing a practical framework for incentives: one that specified the purposes and requirements of an incentive action, identified the goals and objectives of the parties at interest, and developed methods and criteria for evaluating incentives. This practical framework embodied the concepts of the "theoretical framework," but allowed the work, in subsequent phases of the work, to proceed in the environment of the real world. The development of the practical framework was an ongoing process; the approach was evaluated and modified throughout the program as feedback was received from various parties and the interim results were examined.

A major result of this effort was the development of evaluation criteria for incentives, which were used throughout the program. A large number of criteria was developed, relating to the goals and objectives of the program, to the providers and recipients of the incentives, and to the public interests (see Appendix D). These criteria were reviewed by EPA, ETIP, and several pesticide companies. Condensed and refined, they served as broad guidelines for or aids in considering the value of any given incentive or category of incentives by ADL, ETIP, EPA, industry, etc. (see Section IV-D).

(2) Initial Development and Evaluation of Incentives

The first step in this process was the identification of a large number of possible incentives and a brief description of each. These incentives were based upon information obtained in the Task I study on factors of importance to industry, problems posed and incentives suggested by industry and government staff, incentives suggested in the literature, and suggestions of the project core team. Through meetings and discussions of ADL staff, incentive suggestions were combined, and revised, to yield 64 preliminary incentives. These were divided into 12 categories:

- Insurance/Liability;
- IR-4;
- IPM;
- Registration Changes;
- Testing by Government;
- Government-Sponsored R&D;
- Education, Training and Information;
- Funding or Reimbursement of Industrial Development;
- Penalties;
- Market Stimulation/Product Demand;
- Product Protection/Proprietary Position; and
- Other.

Each incentive was described briefly in terms of its goal, the incentive provider (sponsor) and the recipient, and the incentive action. (A summary listing of these incentives can be found in Appendix E.)

The preliminary incentives were discussed at meetings of ADL and EPA/ETIP staff, arguments were presented for and against each, and ADL/EPA/ETIP staff judged each incentive as "good," "bad," or "questionable" with respect to the evaluation criteria (see Appendix F).

Those incentives in the "good" and "questionable" categories were futher examined by individual ADL staff members and in group discussion. Short working papers were prepared on those incentives judged to be "good," each paper consisting of a summary, objective of the incentive, description of the incentive, its implementation, expected observable results, and the requirements for success. Similar papers were prepared for a majority of the "questionable" incentives. (As will be noted later, several of the original incentives that were not developed further are given in Appendix G.)

An "Interim Working Document" was prepared for circulation to a broad range of federal agencies, private companies, organizations, groups and individuals for review and comment. The "Interim Working Document" contained an introduction to the program (giving a brief overview of the EPA/ETIP program goals and objectives), the list of criteria as an aid in evaluating the incentives, a summary listing of the 64 preliminary incentives developed, and working papers on 25 of these incentives. The "Interim Working Document" was sent to about 30 different groups with a request that they review the incentives and provide their reactions to the incentive concept; the type and content of the specific incentive actions proposed; and the desirability, feasibility and impact of specific incentives; and that they suggest modifications to the incentives or new incentives. Because of the amount of work that could be involved and the other commitments of those individuals to whom the report was circulated, any type of response that the group or organization was willing to make was requested rather than a specific evaluation of each incentive with respect to all criteria.

Thirty follow-up contacts[*] (see Appendix H) were made with recipients of the "Interim Working Document," breaking down as follows:

	No.
• Organizations or units within EPA	7
• Departments or units within other federal agencies	5
• Agricultural associations	2
• Pesticide industry manufacturers or formulators	14
• Environmental groups	2

The nature of the contacts ranged from telephone discussions between one ADL staff member and one outside contact to meetings of several hours' duration with from one to three ADL staff members and from one to five persons at the organization contacted. A brief presentation and comment session was held with members of the Federal Working Group on Pest Mangement.

The responses from the individuals contacted ranged from letters indicating that the organization declined to comment to detailed numerical rankings of each incentive according to specific criteria (see Appendices I & J for representative comments on these incentives). The discussions held and comments received were informative, provided insights into the feasibility and desirability of the incentives as perceived by various groups, posed new problems to be addressed by incentives, and suggested additional incentives for consideration. (See Appendix N for additional incentives suggested by industry and government.) Strong reactions to the program and individual incentives, both negative and positive, were the rule rather than the exception (see Section IV-I).

Comments, suggestions, new incentives, and reactions of the outside parties were summarized and circulated to the ADL core team, EPA, and ETIP.

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[*] Contacts defined as a personal meeting; telephone discussion (or letter response) with one or more persons from a single department of a federal agency, a specific company, association, or group.

(3) Final Development and Projection of Incentives

After review of the comments received from industry, government agencies, associations, and public interest groups, discussions were held among the project staff to select incentives for further development. Two processes were used. First, on the basis of the comments received from each organization that reviewed the incentives, a ranking was prepared for each incentive on a scale from 0 to 4 as follows:

Ranking	Comment
0	Can't abide or "live with" incentive
1	Unfavorable toward incentive
2	Neutral (or not necessary) toward incentive
3	Agreed with, but not optimistic about, incentive
4	Strongly support incentive
"blank"	No opinion or comment obtained

(Appendices K-M give the individual and summary rankings.)

In the second process, those incentives that had received the highest rankings were examined and discussed. Several were combined or modified as a result of the comments, suggestions or new incentives from industry, government and other participants.

More detailed papers were prepared on nine final incentives (in many cases two or more related incentive ideas were combined into a single incentive paper). These papers present the view of the project core team of the problems addressed, descriptions of the incentive actions and their possible implementation and impact, and the requirements for success (see Part Two).

An experiment was undertaken to assess the future impact of several of the nine final incentives. With the method developed by Stanford Research Institute for EPA,* the probable acceptance and impact of incentives were examined in a workshop meeting, considering three scenarios representing the different concepts of the political, economic, social, energy, and environmental setting in 1980, 1990, and 2000 (see Section IV-G and Appendix O).

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* "Alternative Futures for Environmental Policy Planning: 1975-2000," EPA-540/9-75-027, Oct. 1975, prepared by Stanford Research Institute, Center for the Study of Social Policy, Menlo Park, Calif.

The process of final development and projection of incentives included a synthesis of the information gained in various tasks and phases, the views of the program participants, and the results of individual tasks, subtasks and analyses conducted in the program.

The final phase of this program is the development and conduct of a conference/workshop to review the program results and incentives and to move toward implementation of those most desirable and useful (see Section IV-H).

IV. RESULTS

A. HISTORY OF PESTICIDE INNOVATION

Although the purpose of the historical investigation was to determine if conditions accompanying pesticide innovation could be repeated through incentive actions, definition of the causative agents was difficult. Most innovations represented a unique nexus of conditions that could be generally grouped as follows:

- A specific need arose.
- Investment resources were available.
- Basic and applied research provided an adequate base for development of the new product.

The pattern of the history of innovations in pest control is characterized by a few important discoveries, followed by a flurry of synthesis activity on similar chemical compounds. For example, the discovery of DDT was soon followed by the related chlorinated hydrocarbons, the ureas, and the triazines. The greatest concentration of innovative activity occurred during World War II, when the three conditions (demand, investment resources, and available technologies) were adequately met.

The sources of funding of innovation have changed considerably. Many early innovative efforts in the development of chemical and biological pest control methods can be traced to government and university research. USDA, NSF, the Rockefeller Foundation, and other sources of funds and manpower continue to be important today, especially in regard to biological controls. However, most of the innovations since 1950 have arisen from industrial research. The European chemical companies were the forerunners, introducing many of the organophosphates and the carbamates. The contribution of American companies has become equally, if not more, important in recent years.

Some of the factors and circumstances that led to innovation in the early history of pesticide development--e.g., fallout from wartime development efforts and major advances in physiologic and behavioral research--are less important today. Instead, the impetus for commercial development of pest control methods has been the high demand for pesticides, the utilization of synthesis, analysis, and screening technology as well as manpower and dollar resources, combined with the competitive nature of the agricultural chemical industry and the financial rewards accompanying successful product development. Increasingly the government has played a role in new pesticide development in regulating pesticides and indirectly affecting research and development. A more detailed account of the history of pesticide development is given in Appendix A.

B. PROBLEMS TO BE ADDRESSED BY INCENTIVES

Factors affecting innovation in industry were examined to point the way for needed incentive actions. Such considerations as profitability, size of market, and proprietary position were found to be critical to industry in R&D decisionmaking. Factors important to industry in product research and development are discussed in detail in Appendix B. The determination of these factors of importance to industry led to the identification of problems in pesticide development. These problems were not only related to innovation, but included other critical situations that might be appropriately addressed by incentives in order to meet the goals of this program.

Problems created by regulatory activities:

- The time required for pesticide development has increased due to the tests required for pesticide registration, as well as the time required for EPA's review of registration applications.
- Registration testing requirements have increased the cost of pesticide development.
- The "climate" in which a pesticide is developed has become increasingly unstable due to the uncertainties surrounding requirements for registration and reregistration.

Problems connected with market size:

- The high investment required (due to registration) and the low return on investment in pesticides for minor crops often prevents the development of pesticides for minor use alone.
- Liability is a potential problem in developing pest control products for the protection of high-value, low-volume crops and for the home and garden market.
- Company policy dictating the need for a "big winner" neglects the smaller markets.
- The work of IR-4 is hampered by the unwillingness of many companies to register products cooperatively, and by the large volume of registrations requested each year through the IR-4 program.

Problems connected with proprietary position:

- The lack of protection for naturally occurring materials is considered a barrier by many companies.
- The transfer to companies of ideas or products developed by the government or universities is very difficult as a result of patent problems.

- The loss of patent life due to registration requirements for all types of products, but especially innovative ones, is a problem.

Although these problems were mentioned by various sectors of industry, there was little agreement within industry and within government concerning the details of these problems. There is, however, general agreement on several issues. Both industry and government believe there is a "minor use problem" although they may disagree as to the nature of it. Most parties will concur that registration requirements have affected the cost and time of product development. Whether this has impacted innovation is not clear. Other issues are even less clear. Does liability, although often mentioned, affect manufacturers' decisions? Does a patent life, shortened by registration requirements, prevent pesticide development? These issues were all considered in the development of incentives.

C. CONCEPTUALIZATION AND DEVELOPMENT OF INCENTIVE FRAMEWORK

Developing the concept of government-sponsored incentives to aid in the solution of these problems was the focus of most of this program. Past government-sponsored incentives have ranged from slogans recommending the purchase of government savings bonds, to cost-sharing of highways and buildings under grant programs, to tax incentives.

In this program, an incentive was considered to be an action (or behavior) taken by one organization or person--the incentive provider--in order to attract or convince another organization or person--the incentive recipient--to take other actions (or change behavior) so as to meet some of the goals and objectives of both incentive providers and recipients. In addition to incentive providers and recipients, intermediaries often facilitate the implementation of the incentive, and may obtain benefits which help meet their own objectives. Principal incentive providers, intermediaries, and receivers considered in this program are shown below:

Providers	Intermediaries	Receivers
Congress	State agencies--university and agricultural experiment stations	Pest control industry--manufacturer, formulator
EPA		
		Pest control R&D sources--industry, university, independent laboratory
Other federal agencies	Industry and User Associations	
	Federal agencies	Pest control users

Several different types of incentives were considered:

Administrative/regulatory	changes in administrative procedures, regulations, guidelines, program assignments, etc.
Funds	direct or indirect funding, credits and subsidies
Service/function/facility	resources offered in kind, e.g., use of federal facility, federal testing, etc.
Manpower/training	provision of personnel resources for training or other purposes
Information/data	providing, organizing, or evaluating data needed by recipients
Consumer/market	indirectly or directly aimed at creating or changing market demand

Among these various types of incentives, some may be more appropriate than others (and more successful) in addressing specific problems. Further discussion of the incentive concept is given in Appendix C.

An incentive need not meet all goals of the providers or recipients, and indeed these goals may be in conflict. However, for an incentive to be successfully implemented, at least one specific objective of the provider and recipient must be met. Similarly, objectives of the various parties usually vary, covering a range from simple, specific and, near-term objectives to complex, broad, and long-term ones. An incentive may address only a near-term objective but still have ultimate impact on a broader, more long-range objective.

A successful incentive must also meet criteria such as those shown in Table 3. These criteria were used to help evaluate the potential acceptance and impact of proposed incentives. Additional criteria for incentives are given in Appendix D.

D. INITIAL DEVELOPMENT AND EVALUATION OF INCENTIVES

1. Preliminary Incentives

On the basis of contacts with government and industry--both under this and earlier contracts with EPA--and as a result of Task I and the development of an incentive framework, a set of preliminary incentive ideas was developed. These were of considerable breadth and diversity, reflecting the various perspectives and opinions of the many parties at interest.

TABLE 3

CRITERIA FOR EVALUATION OF INCENTIVES

Does the incentive address the goals of improved environmental and human safety of pest control agents and use practices--

- promote pest control methods that are increasingly
  - non-toxic to non-target organisms
  - non-mobile and non-bioaccumulative
  - narrow spectrum
  - non-persistent
- promote biological control, integrated pest management and other non-traditional chemical pest control approaches

Does the incentive help maintain or develop an adequate supply and variety of pest control methods for all important pest problems--

- increase variety and availability of pest control methods by stimulating innovation
- encourage development of pest control methods for minor crops and markets
- maintain viability of the pest control industry including existing R&D resources
- maintain diverse resources for pesticide research and development

Will the incentive help the pesticide industry--

- improve profitability and return on investment
- encourage new corporate entries
- enhance pesticide markets--size, penetration
- reduce the time and costs of pesticide registration and/or development

Will the incentive help agriculture and other pesticide users--

- maintain or improve unit profitability of agricultural production
- have increased access to effective pest control methods for a minor use/crop application

Table 3 Continued

- lower the risk of achieving profitable crop yields and/or utilizing best management practices
- have access to more effective, safer, and inexpensive pest control methods

In terms of feasibility, will the incentive:

- be simple to implement
- use existing organizational resources and mechanisms
- avoid prohibitive expenditures for any party
- achieve the desired goal, if implemented, or are there significant risks or uncertainties
- be reasonably self-sustaining once initiated
- *by itself* have sufficient impact to warrant its adoption

Will the *incentive be acceptable* to the

pesticide manufacturer
pesticide formulator
pesticide distributor
pesticide dealer
pesticide farmer/user
EPA
USDA
Congress
public
environmentalist

Will the real *tangible benefits accrue* to the

pesticide manufacturer
pesticide formulator
pesticide distributor
pesticide dealer
pesticide farmer/user
EPA
USDA
Congress
public
environmentalist

Will the incentive

- be *implemented in the near term* (1-3 years)
- produce any *useful results in the near term* (1-3 years)
- produce *worthwhile longer term results* (4-10 years)

Incentive ideas were discussed among the project staff, some suggestions were revised and combined, and a set of 64 preliminary incentives resulted. These were grouped into 12 action categories:

Insurance/liability
IR-4
Integrated Pest Management and Biological Control
Registration
Testing by Government
Government-Sponsored R&D
Education, Training, and Information
Funding and Reimbursement of Industrial Development
Penalties
Product Protection/Proprietary Position
Market Stimulation/Product Demand
Other

(The 64 preliminary incentives are listed and briefly described in Appendix E.)

2. Initial Screening

Initial screening of these incentives consisted of discussion and evaluation with respect to the evaluation criteria described above and presented in Appendix D. ADL, EPA, and ETIP staff informally screened the incentives by choosing those that seemed feasible and effective in meeting a particular goal. The complete results of the initial screening process are given in Appendix F.

3. Working Papers

The incentives that emerged from the screening process were explored further; a working paper was prepared for each one in sufficient detail to stimulate evaluation and discussion by ADL, ETIP, EPA, and outside reviewers. The working papers on incentive ideas that were not incorporated in the final incentives developed in this program are given in Appendix G. All working papers, along with background materials and criteria for evaluation, were contained in an Interim Working Document.

4. Review of Incentives with Government, Industry, and Interested Parties and Final Ranking

The Interim Working Document was distributed to 17 companies, 18 government agencies, and 9 other interested parties for review. (See Appendix H for list of organizations who received the document.) The specific comments received concerning the incentives proposed in the Interim Working Document are listed in Appendices I and J. Based upon these comments and discussions with the organizations, the program staff prepared rankings by industry, government agencies, and associations (see Appendices K, L, and M) on a scale of 0-4 indicating relative acceptability as follows:

0 can't abide or "live with" incentive
1 unfavorable toward incentive
2 neutral toward incentive
3 agree with, but not optimistic about incentive
4 strongly support incentive

Table 4 lists the ten incentives with the highest average rating by industry respondents and the ten with the highest rating by representatives of government agencies and associations.

Industry representatives were more enthusiastic about a smaller number of incentives than were the respondents from government and associations. Industry favored most those incentives dealing with costs, time and uncertainity of registration, patent life and crop groupings. Government and association rankings were more uniform and favored most those incentives dealing with research, training, and ongoing government programs. Several incentives were rated in the top ten by both groups--reducing the time and cost of registration, crop groupings for minor crops, supplemental funding for IR-4 program, and expansion of the extension service.

A number of additional incentives were suggested during the discussions with industry and government staff. Some of these were incorporated into the final incentives developed in the program. Appendix N lists the specific incentives suggested by those who reviewed the Interim Working Document.

5. Critical Issues

In the process of developing and evaluating incentives, and in considering methods for implementing them, a number of important issues were raised with EPA/ETIP personnel and with government, industry and other interest groups. Viewpoints differed considerably; many issues could not be resolved to the mutual satisfaction of the various parties. Assumptions had to be made concerning some of these issues in order to proceed with the development of incentives. However, the actual resolution of these questions will be a major determinant of what incentives are implemented and, in some cases, in what manner.

- Who Should Sponsor Incentive Actions?

That the principal issues and problems can best be dealt with at the federal level was a major premise of this program.

However, should EPA sponsor most incentives? One viewpoint is that regulations have created many of the problems that are being addressed by incentives and that EPA should be responsible for their resolution. Furthermore, since EPA, by virtue of its pesticide regulatory role, will ultimately have to deal with pesticides and their effects on man and the environment, it should also influence future research and

TABLE 4

INCENTIVES THAT RECEIVED THE HIGHEST AVERAGE RATING BY RESPONDENTS FROM INDUSTRY, GOVERNMENT AGENCIES, AND ASSOCIATIONS

Incentive		Average Rating
	Industry	
20.	Reduced Time and Cost of the Registration Process	3.9
19.	Decreased Uncertainties of Registration Process for Applicants	3.6
49.	Modification of Patent Issue Date and/or Duration	3.6
9.	Crop Groupings for Minor Crops	3.3
35.	Definition of Standards for Safety	2.8
39.	Improvement in the EPA Contacts with Congressional Overseers	2.5
7.	Supplemental Funding for IR-4	2.5
41.	Research Investment Credit	2.3
58.	Expansion of Extension Service Program	2.3
16.	Reduced Registration Time for Safe Products	2.2
	Government Agencies and Associations	
58.	Expansion of Extension Service Program	3.4
14.	Reorganization of USDA Research on Biological Control	3.3
37.	Independent Pesticide Research Foundation	3.3
60.	Expansion of the Number and Role of Independent Pest Management Consultants	3.3
36.	Training of Farmers and Applicators	3.0
61.	Safety Index	3.0
7.	Supplemental Funding for IR-4	2.9

TABLE 4 (Continued)

Incentive	Average Rating
9. Crop Groupings for Minor Crops	2.9
20. Reduced Time and Cost of the Registration Process	2.9
43. Reimbursement of Registration Costs for Pesticides for Minor Crops	2.8
44. Repayment Loan Fund for Pesticide R&D	2.8

development efforts so that there are fewer regulatory problems in the future. On the other side of the argument, regulation of pesticides may be compromised by involvement in product development.

Another viewpoint is that the sponsor should be the federal agency "closest" to the problem area. Since one criterion for the success of an incentive is that direct benefits accrue to the sponsor, logically different agencies should sponsor different incentives. For example, USDA might sponsor incentives dealing with the use of pesticides or on behalf of agricultural users of pesticides. The Department of Commerce might best sponsor incentives dealing with generic industry problems, such as patents, copyrights, and trade secrets, with EPA sponsoring only those incentives concerned with pesticide regulation. This approach would help ensure that the incentive sponsor is one who is "trusted" by and has common goals with the recipient, and that a reasonable working relationship exists or can be developed between sponsor and recipient.

- Should EPA be a Pesticide Promoter as Well as a Pesticide Regulator?

One of the reasons often cited for transferring pesticide regulatory authority from the USDA to EPA in 1970 was that the relationship between the regulating agency and the regulated industry had been too "close" and that a conflict had existed between USDA's regulatory objective and its promotional objectives, i.e., increased agricultural production through development and use of pesticides. EPA, on the other hand, is an executive and regulatory agency, with OPP implementing a law that seeks to prevent unreasonable adverse effects of pesticides on man and the environment. Many persons believe that EPA should avoid a regulatory and promotional conflict and that other agencies, not EPA, should provide incentives that promote development of new pesticides.

However, FIFRA acknowledges that a balancing between the benefits and adverse effects of pesticides must be considered in the regulatory process, and some interpret this to mean that EPA/OPP must act to ensure that the benefits of pesticides continue to be available whether through regulation or through encouragement of the development of new pesticides.

- Should EPA Give Priority to Certain Products in its Regulatory Activities?

There is much disagreement about whether EPA should treat "safer" products preferentially. On one hand EPA's mandate is to ensure the use of safe pest control methods, perhaps through the mechanism of giving priority in registration to safer products and thereby discriminating against other products that meet existing standards. The law requires that OPP give priority in its research to the development of biologically integrated alternatives for pest control. On the other hand, one cannot, a priori, assume that biological controls are safer than other pest control methods. Should OPP give regulatory priority to biologically integrated alternatives in order to encourage private development of these products?

- Should the Government Conduct Research on or Test Pesticides?

A significant number of the incentives originally proposed in this program dealt with government conduct or funding of research on pesticides or tests required for pesticide registration. As anticipated, the general reaction from both industry and government was that government funding was better than government conduct of research and testing. Various reasons were cited: inefficiency in government organization, delays in testing, lack of motivation for initiative efforts, etc., if the government performed the functions. Industry was generally opposed to government funding of tests required for registration, since this could result in loss of control over the product development efforts, and most government agencies also believe that industry should continue to be responsible for testing.

The effectiveness of government-sponsored and conducted research has been a subject of debate by many. The current view of many individuals and groups (including ETIP's) is to have the research conducted by those who have the greatest potential for reward from exploitation of the research results. The past history, accomplishments, and structure of the pesticide industry indicate that industrial research may lead more directly to new pesticide products. Another viewpoint is that the government should perform high-risk research that industry is reluctant to perform or research that is necessary only because of government-created needs.

- Are the Long-Term Risks to the Pesticide Industry Increasing?

Many pesticide companies and users and government representatives feel that regulations and other factors increase the long-term financial risks of the pesticide business and thus lead to changes in the industry that may adversely affect the country's economy and agricultural output.

The uncertain impacts of pesticide regulations on the quantity and effectiveness of pesticide research and development have already been discussed. EPA and OSHA requirements for control of air, water, and solid waste effluents and the working environment have demanded changes in manufacturing processes, waste treatment, and storage and disposal. Other costly changes include:

- New data or personnel requirements, additional tests, review, process changes, new label requirements, etc.
- Efforts devoted to defense of existing products, in suspension and cancellation processes and litigation, and in responding to the Rebuttable Presumption Against Registration (RPAR) process, as well as in justifying reregistration of pesticides.
- Lost sales as a result of new experimental permit procedures, state registration changes, delays in issuance of registration, and suspensions or cancellations.

These factors are believed by many to lower the potential for profit in specific pesticide production and for specific pesticide companies. In addition, the longer time required for registration and the higher chemical construction costs increase the payout period (or reduce the internal rate of return) on individual products or for company ventures. An increasing financial risk in the pesticide industry may persuade investors and managers to devote their efforts and funds to more secure ventures.

The high cost of entering and maintaining investment in the pesticide business also suggests that the industry is likely to consolidate--large companies becoming larger, smaller organizations withdrawing from the field or merging with others. This consolidation in itself may not be detrimental, but some persons believe it can reduce innovative efforts in pest control.

On the other hand, registered products that enter the marketplace may have a greater profit potential and long-term return because of the many products that are either not registered or are canceled. Thus, the present processes and trends tend to make larger "winners" of fewer pesticide products. Further higher costs of development and regulation are countered by increases in sales resulting from the increased reliance on insecticides, herbicides, and fungicides, and from the users' willingness to pay higher prices for them.

- Who Wants Incentives?

The purpose of an incentive is to cause a particular action or reaction to occur. A recipient is more favorable if he perceives real benefits from an incentive.

In general, the pesticide industry and perticularly the larger organizations are suspicious of accepting government-sponsored incentives because of possible additional and unwanted government intervention or regulation.

Federal agencies tend to favor providing incentives if they help achieve the goals and objectives of the agency, can be used to develop a new program or expand an existing one, can be accomplished within reasonable budgets, and will improve the agency's public, congressional, and executive image.

Pesticide users are most likely ambivalent to incentives, and may not have significant influence over their adoption. They will be in favor of incentives which can help provide them with the needed variety of safe cost-effective products, and be opposed to those which decrease pesticide availability or increase pesticide costs.

- **What Type of Interaction is Appropriate Between Government and Industry?**

This issue is not unique to the pesticide industry or to pesticide regulation; much has been written on the interactions of the pharmaceutical industry and the FDA, the airlines and the FAA and CAB, etc. The comments obtained from various parties suggest that an idealistic view of the interaction between the government (OPP as the regulator in this case) and the pesticide industry would be one which: recognizes the divergent as well as the mutual goals of the parties and respects each other's viewpoints; establishes mutual confidence through utilization of staff with appropriate skills, professionalism, and attitudes; is straightfoward and open in intent, information transfer, and procedure; and considers the views of other parties affected by the interactions. Some believe that a strictly adversary approach is essential to assure a proper balancing of all parties' interests and to bring issues to a definitive resolution.

- **Who Should Pay for Incentives?**

Almost any incentive that can be expected to have an impact on the current problems of pesticides and pesticide regulation will cost money. Funds will be required to administer the incentive, to pay for staff of the agency or industry providing or responding to the incentive, or to conduct the work required by the incentive. Those incentives with low total cost are favored by Congress, government agencies, industry, and the public, provided they also have significant benefits or impacts.

Although the general belief is that the costs should be borne by those who benefit from the incentive, it is more difficult to identify the beneficiaries and levels of benefits and allocate costs accordingly. Furthermore, there is a question of transferring costs from one group to another. If EPA embarks on a program of pesticide research, information exchange, and change in regulations, the costs will most likely be paid ultimately by the general public through taxation. Yet the government, industry, and pesticide users will be the primary beneficiaries; the public will be a secondary beneficiary through less potential for environmental or personal hazards, maintenance of food supplies, etc. Similarly, if industry responds to incentives by new research efforts, development of new products, added test procedures, etc., the cost will ultimately be transferred to the consumer and the public. Although it seems inevitable that the costs must be borne ultimately by the public, the direct responsibility for funding has been suggested for each incentive developed in this program.

E. FINAL INCENTIVES

Nine incentives addressing specific problems were selected for more careful and detailed consideration. Short essays have been prepared exploring the problems addressed by, the background for the specific actions in, and possible results of each of these nine incentives.

Because collectively these papers are quite long, they are not presented here, with the other results of this program, but rather separately in Part Two of this report.

The reader is encouraged to peruse several (if not all) of these nine incentive papers and the following brief descriptions are provided as an indication of the problems addressed by them:

(1) Increase Availability of Minor Use Pesticides

A lack of pest control methods for some low-volume crops has resulted from the high costs of product registration and concern about liability. Suggested actions would administratively facilitate the registration of pesticide products for minor uses and evaluate possible liability problems further.

(2) Increase Utilization of Integrated Pest Management

Three action areas are suggested to further the use of an appropriate combination of pest control techniques rather than exclusively chemical means of control: expansion of the use of corrective pest control, investigation of current obstacles to user acceptance of IPM, and funding of projects utilizing diverse pest control techniques.

(3) Decrease Regulatory Hindrances to R&D

The implementation of FIFRA, as amended, is expected to hinder industrial R&D of pesticides. Suggestions are made to reduce the time (and costs) of the registration process, the costs of registration test requirements, and the difficulty of R&D decisionmaking in changing regulatory environment.

(4) Increase Government Support of Basic Research

Increased government funding of basic research is proposed as a means of stimulating novel applied research concerning pest control.

(5) Increase Information and Training for Users

In order to increase the market demand for improved pesticides, an expanded program of information and training for pesticide users is proposed to be coordinated at the state level through the USDA Extension Service.

(6) Lengthen Patent Life

Because the registration process has effectively shortened the period in which a company can recoup its investment in a pesticide product, suggested changes in the patent laws would extend the patent life of such products.

(7) Improve Communications Between the Pesticide Industry and EPA

In order to achieve better mutual understanding and possibly increased efficiency of pesticide registration, the establishment of informal joint industry/EPA committees is suggested.

(8) Advertise Safety on Product Label

Suggested changes in the wording on pesticide product labels would enable users to choose less toxic products and could lead eventually to a greater demand for such products.

(9) Reduce the Risk of Product Development by Industry

Administrative and policy changes within EPA and increased participation by industry and the public are suggested as a means of establishing a climate in which R&D can have more certain returns over the long term.

F. OTHER PROMISING INCENTIVES

In the final stages of screening and evaluation, several other incentives were believed to have potential for success. Some were incorporated into the nine final incentives presented in Part Two. Others were not developed further in order to concentrate on those with greater potential. EPA and other organizations may wish to investigate these more fully. Following is a brief description of six of these incentives and some of the reactions of various groups.

(1) Research Investment Credit

The purpose of this incentive is to encourage additional investment in pesticide R&D by private industry. On EPA's recommendation, Congress would pass a tax abatement scheme similar to the current investment credit, allowing companies to offset their income tax by a certain percent (perhaps 10%) of all or certain of their research expenditures on pesticides during that tax year.

In spite of generally favorable reactions by program participants to its intent, this incentive was considered to have a low probability of success. Several companies felt such credits would reduce some of the cost of added R&D burdens; others were fearful that the implementation would open the door to government direction of research. The problems of allocation of research costs and the required bookkeeping and accounting were considered drawbacks. Such a measure would have to be passed by Congress and would probably have to include all highly regulated industries, not only the pesticide industry. The probability of this happening is low.

Government agencies and environmental groups cited the difficulty in administration, and the increase in complexity of the tax structure.

(2) Insurance/Liability

Several incentive actions were proposed to counteract the adverse effects of "product liability" on pesticide research and development.

- Insurance for Minor Crops--The federal government would create an insurance program to reduce companies' liability for product-related damage to low-volume, high-value crops or for other minor pesticide uses. A federally sponsored re-insurance program was an alternative to compensate for catastrophic losses on minor crops.

- Insurance for Farmers Using Improved Pest Control Methods--The USDA would extend the crop insurance program to reimburse farmers for crop losses resulting from the use of new, innovative pest control methods, formulations or application methods.

- No-Fault Tolerance--USDA and State Experiment Stations would develop "guaranteed" residue and phytotoxicity data which could be used in registration. Companies would not be liable for crop losses in a specified period after registration if these data were used.

Most companies and trade associations and some government representatives did not favor (or favored only limited) government-sponsored insurance incentives because they believed:

- "liability" was a "proper risk" of doing business;

- such incentives might stimulate less than desirable performance by industry;

- federal involvement could lead to a costly and complex program;

- gross misuse of such incentives, in the form of false claims, could occur;

- any program would be difficult to implement and administer; and

- existing re-insurance systems are adequate and catastrophic losses are infrequent.

Some goverment groups consulted favored replacing "chemical insurance" with "dollar insurance," believing that such incentives could help to solve the minor use problem and could be added to existing crop insurance programs.

Further study is needed to quantify the impact of product liability on availability of pesticides for minor use or on research and development of new products.

(3) Government Generation of Environmental and Residue Data for Minor Crop and Specialty Pesticides

The goal of this incentive is to extend the IR-4 program to provide for government generation of environmental data, as well as residue data in order to reduce development costs. Industry would be required to develop toxicity and efficacy data prior to government testing.

The extension of the IR-4 program to address the minor use problem is addressed by one of the final incentives. Industry reaction to this specific approach was mixed. Companies disagreed concerning the effectiveness of USDA as the sponsoring agency and whether testing should be performed by independent laboratories, rather than government laboratories, or by industry itself. Some felt that the current IR-4 program was sufficient and such a process would increase registration time. Government reaction was similarly also mixed.

(4) Government Funding of Research on Formulation and Application

This incentive calls for increased government-sponsored research on methods of formulation and application under the direction of a USDA-EPA committee, assisted by a user-industry advisory group. Research projects, conducted by university and extension service staff, would emphasize close cooperation among pesticide users, equipment manufacturers, formulators, and the pesticide producers. This would hopefully lead to better control of pesticide use, more cost-effective application, enhanced applicator safety, and reduced environmental hazards.

Industry had mixed reactions to this incentive. Some companies felt the research should be sponsored only by USDA and should be limited to application methods. Others felt that this research was already conducted by both industry (formulators) and government (states and USDA) or that industry was best suited to do the research.

Government agencies generally favored the continuation of current research practices, in which USDA, state agenices, and universities conduct application research with most formulation research accomplished by industry. Some government agency staff felt this work would constitute interference in the market by government.

(5) Commercialization of Pesticide Products Developed by or for the Government

Studies of pesticide innovation and factors of importance to the pesticide industry suggested that new product research and development conducted by the government was rarely "picked up" by industry, even though significant expenditures had been made and some of the development risks had been mitigated. The objective of this incentive is to encourage industry to exploit pesticide technology that has been developed by, or under contract to, the government, through granting industry exclusive licenses to government-owned patents or facility-development contracts for limited pesticide production. Priority could be given to "biological control" approaches.

Industry reaction was again mixed. Some companies favored the incentive if: biological controls were not emphasized, potential products were "sold to the highest bidder," or if products with real potential could be developed by the government. Others were skeptical, doubting that the incentive would have significant impact and believing that new product development should remain in the domain of industry.

Government agencies generally favored the incentive, but felt that the public would view the incentive as "subsidizing industry," although any good potential product should be offered to industry for further development.

(6) Expansion of the Number and Role of Independent Pest Management Consultants

The role of the independent pest management consultant has been increasing in the western states, particularly in California. Several studies have been conducted on the benefits and costs of pest management consultants.* The USDA or EPA would support, through training and subsidies, an increase in the number of independent pest management consultants who counsel farmers and growers, aiding in the selection and application of pest control measures.

Some industry representatives favored this incentive if IPM were not a requirement of the program, if USDA or the SBA (not the EPA) implemented the incentive, and the expense to the taxpayers was minimized. Others felt that it was the private sector's responsibility to develop such services if they were needed. Some government representatives felt that the only role for government was to provide information and that the private sector should be responsible for using the information. Those who favored the incentive felt that it should be implemented by USDA or SBA, not EPA. Other groups felt that these services would be in direct competition with the state extension services and inhibit both programs.

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* See, for example, Willey, Wayne R., "The Diffusion of Pest Management Information Technology" (Ph.D. dissertation prospectus, University of California, Berkeley, March 1974).

G. THE FUTURE PROSPECTS FOR INCENTIVES

1. Introduction

One of the goals of this program was to assess the potential impact of the incentives on pesticide research and development in the next 25 years. The near- and long-term impacts of the incentives are difficult to evaluate because of the complexity in assessing the acceptance of incentives by various parties, the information that will be developed in the future on the benefits and costs of pesticide use, and the potential changes in the social, economic, agricultural, and environmental status of the nation. Therefore, instead of extensive effort devoted to estimating future impacts of incentives, the analysis of the period 1980 to 2000 was limited to the potential acceptance and impact of several incentives and the incentives program itself based on three scenarios* for the future developed by the Stanford Research Institute. The scenarios cover three major themes: relative industrial success with no major value or institutional changes from the present; industrial distress that results in social, economic, and political instability; and an industrial transformation. The results are summarized below; additional detail is given in Appendix O.

2. Analysis of Incentives

In the highly successful and industrial scenario, those incentives that benefit industry the most will be accepted to a greater degree than at present. This is entirely the expected trend. Incentives that lower the power of regulation or place more emphasis on industry's meeting user needs with minimum environmental concerns will be acceptable. The impacts of these incentives will be equal to or smaller than at present because of the power of the industrial establishment and the fact that pesticide problems probably will be resolved through technology which will be developed with or without incentives.

Under a scenario in which there is a major transformation from today's values to those associated with a more frugal society, those incentives that deal with individual choices, benefits to the small companies or directly to users, and biologically integrated alternatives will be more acceptable than at present. Such action will probably have a greater impact because of the individualistic nature of society in this scenario.

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*SRI developed ten scenarios; the three chosen represent optimistic, moderate, and pessimistic views of the future. They are referred to by SRI as Hitting the Jackpot, the Dark at the Top of the Stairs, and Journey to Transcendence.

In a scenario that represents breakdown and ultimate failure of our political and economic institutions, none of the incentives examined in this analysis shows promise of greater acceptability or impact than at present. More important problems will be faced by individuals, existing industrial organizations, and society than the long-term aspects of development of new pest control methods, even when food shortages occur. By that time, immediate needs will take priority and little effort will be devoted to future concerns.

The acceptability and impact of incentives in different scenarios and in different time periods was examined. The results of this examination indicated no course of action that would be promising in all scenarios. Thus it is not possible to design a policy of incentive actions that is appropriate for all eventualities.

Conclusions that can be drawn from this analysis are as follows:

- There is some risk in implementing incentives no matter what course EPA chooses but this risk can be reduced somewhat by monitoring of signs that society is taking one path to the future or another.

- The incentive actions least vulnerable to uncertainty are changes to the registration process and the advertising of safety on the label, but the uncertainty in these increases toward the year 2000. This implies that action should be taken now, if at all.

- General acceptance for the objectives of the incentives program is mixed at present, uncertain in 1980, and becomes negative in the year 2000. This strongly suggests taking action now, if at all.

3. Examination of the EPA/ETIP Program

In considering the EPA/ETIP incentives program in the futures concept, the acceptance of such a program is probably greatest now, under the economic and societal conditions which presently exist. This is attributed to the assumption that most of society believes there are still time and methods available to solve problems of pest control costs and benefits. The split in values today is such that persons with differing views and values can see benefits from an incentive program, and thus can support the program even though their goals may differ considerably. Thus, in the absence of great food, energy, political or social crises, one can expect strong support of government programs to improve the efficiency of govenment, help industry meet some of its needs, and solve some public problems.

If a highly successful technical/industrial society evolves, either the problems of pest control will be solved or those individuals outside this mainstream society will have neither the desire nor the power to change the system via an incentives program.

In a society that involves transition to frugal values, there will be less demand for a program which seeks to continue industrial development of new pest control approaches. In the early years of this transition, a program of incentives aimed at the needs of individuals might be accepted, but as individual needs change and as society changes with them, both the government structure which can create incentives and the benefits to be gained from such incentives will be of little importance and use.

Incentive programs might be useful in a future scenario in which institutional degradation and social decay are evident, and could help overcome such trends. However, if external variables are strong enough to drive the society further toward the brink of social and economic disaster, incentive programs will be of no value--much more important survival and political issues will consume the energies of the public.

The public's attitude toward the individual goals of the ETIP/EPA program may change. For example, alleviating the problems of regulation will be highly acceptable in a technological/industrial society, but it is doubtful that the pesticide regulations that would continue to exist in such a society would pose significant problems for industry. Assistance in the development of safer, biologically integrated products can have greater acceptance and impact in a transformation scenario than in other scenarios.

An incentive program has less importance, less acceptance, and less impact as technology is able to meet the problems of pesticide use. Where major societal changes take place rapidly, long-term programs--e.g., incentives for R&D of new pesticides, which cannot be expected to give results for at least ten years--will have less acceptance than at present.

H. INCENTIVE CONFERENCE AND WORKSHOP

At a conference on October 26 and 27, 1976 in Gaithersburg, Maryland, representatives of the parties at interest were assembled to examine and evaluate the incentives that had been developed. Of the approximately 100 attendees, 75% represented the agricultural and chemical industries and the remainder represented government agencies with some jurisdiction over pest control. A series of workshops were held during which the meeting participants evaluated specific incentives and attempted to develop a consensus concerning implementation steps and the responsibilities of specific agencies or groups.

The proceedings of this conference/workshop and an evaluation of the results of the discussions have been published separately.*

I. REACTIONS OF THE PROGRAM PARTICIPANTS

Throughout this program, the staff received excellent cooperation and extensive assistance from a broad range of industrial, government, user, and public interest organizations and groups. Much of the information they provided on factors of importance in pesticide development and comments on specific incentives, has been incorporated in this report. Appendices I and J provide the comments of various participants on each of the incentive actions originally proposed. The following pages sum up the reactions of the major participants to this program, prior to the Incentives Workshop, both pro and con. (See Incentives Conference Summary for reactions of the participants in the workshops to the incentives finally selected for presentation.)

Reactions to the program, the need for incentives, and the specific incentives were many and mixed. They ran the gamut from strongly opposed, to neutral, to strongly favorable.

Many of the negative reactions are believed to result from some combination of:

- A general disbelief that EPA really desires to balance the benefits and costs of pesticide use.
- The inability of EPA (or our team) to convey the diversity of its goals as a regulatory agency with regard to the need, development, use, and regulation of pest control methods.
- The viewpoint that any government intervention in the "domain" of industry, however well intended, is costly, ineffective, and unnecessary.
- The belief by some environmentalists that EPA is "not doing enough" to protect man and the environment from the dangers of potentially hazardous substances such as pesticides.

On the other hand, many positive reactions stem from the sincere desire of many groups to attempt to resolve the issues of the "pesticide conflict" for the public benefit.

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* "Developing Incentives for Pest Control Methods." Proceedings of a Conference. Arthur D. Little, Inc., under Contract 68-01-3133 to Office of Pesticide Programs, U.S. Environmental Protection Agency and Experimental Technology Incentives Program, National Bureau of Standards, 1976.

1. Industry Reactions

In general, the reaction of 14 industrial participants contacted was negative or "guarded" both to the incentives program and to most incentive actions suggested. For example, two major pesticide companies participated originally in the work on factors of importance to pesticide R&D, but declined to comment on the incentives in later stages of the program. One organization felt "the pesticide industry was thoroughly capable of meeting reasonable regulatory requirements and that an incentive program was not needed," and that "a government-managed program of incentives was contradictory to the free enterprise system." They also "do not believe EPA is sincere in its proposed development of an incentive program for the pesticide industry."

A second company declined to comment on the basis that it believed "more regulations will follow any government-sponsored incentive program." This company indicated "industry did not ask for such incentives, does not need them, and does not want them, and that incentives would not solve any problems resulting from overregulation." This company felt that "industry needs most from government a cooperative effort in the development of scientifically sound regulations realistically satisfying the mandate of Congress coupled with the expeditious determination of compliance therewith."

Another organization, indicated disappointment with the incentives in general. It categorized most of the original incentives presented as impractical, uneconomical, already being done, marginally helpful, and only some as worth further evaluation. Another company staff expressed dissatisfaction with the incentive program, felt that it should not be conducted, and thought that EPA was causing great hardships for the industry. Despite the negative responses, the latter two companies did comment constructively on several specific incentive actions which we proposed and suggested several new incentives.

Other reactions by industry were more moderate. Many organizations carefully reviewed each incentive proposed, presented detailed comments about their needs, and about the incentive's acceptance, benefits and potential problems. They were anxious to cooperate in the program and strongly supported incentive actions concerned with: improvements in the registration process, training and education, communication, patent issues, liability, clarification of test procedures, resolution of "proprietary data" problems, and changes in attitudes of regulatory and industry staff. Several new incentives were suggested in these areas. These organizations stressed the need for confident and competent decision-making, risk-benefit analysis, openness of communication and information, and separation of regulatory and promotional pesticide activities of the government.

However, they also expressed a general concern that many incentive actions originally proposed would ultimately lead to more regulations and more government intervention. They were suspicious of the "conflicting and diverse goals" of EPA, of the promise to balance the costs and benefits of pesticides, and of the likelihood that EPA could and would do anything that could help industry. They doubted that many incentives would be implemented by the government, even if they would help solve some current problems. They did not support any incentives which addressed government testing, direct government support of private research, programs financed through taxation, or government intervention in marketing or stimulation of product demand.

Finally, several organizations expressed enthusiasm for the incentives program and for specific incentives. These groups believe that implementation of specific incentives could help them in overcoming some of the problems resulting from regulations and could aid in some of their R&D activities.

The response of industry associations was similar to that of the larger individual companies, i.e., primarily negative towards or skeptical about any benefits that could accrue to the pesticide industry.

2. Government Reactions

Most government agencies favored the incentive program and many of the individual incentive actions. However, there was considerable disagreement among the various agencies and to some extent within different parts of EPA about the role of the different government agencies in pesticide regulation, pesticide research and development, and information and training related to pesticide use. Some strong arguments were presented about the need to restrict EPA's role to regulation, with counter arguments that all pesticide efforts should be focused in a single agency to foster effectiveness and economy.

The conflicts among EPA and other agencies associated with the use of and research on pesticides (e.g., USDA and Department of Interior) was evident throughout our discussions with government agencies. This conflict generated some of the same concerns and issues as described above for industry, particularly whether or not EPA should pursue somewhat divergent goals of strict pesticide regulation to protect against adverse effects, adequate balancing of costs and benefits of pesticide use, and encouragement of the use of more safe pest control products.

In general, government agency staff believed that:

- Incentives should not include changes in regulations or other accommodations to industry that would lower or restrict environmental standards;

- Incentives should encourage government-sponsored R&D that would result in cost effective research efforts;

- Incentives should not increase government intervention in pesticide R&D except through regulatory related areas--for example, government testing of pesticides was not favored;

- Incentives should be low cost, and be able to be implemented through a single federal agency if they are to be successful; and

- Incentives should be associated with training and education, solution of the minor use problem, market stimulation, and encouragement of IPM.

3. Reactions of Environmental Groups

Environmental groups, in general, were enthusiastic about the incentive program, especially those incentives that would encourage the use of safer products and biological controls. They disagreed with the assumption that the pesticide industry needed incentives for the continued development of pest control methods. They were particularly concerned about the effect incentives would have on EPA's ability to maintain a strict regulatory stance.

Some of their specific reactions were:

- Because of their familiarity with legislative activity, they were particularly aware of the difficulties in obtaining congressional funds for some of the incentives. They also identified difficulties in defining terms and setting criteria for decisions involved in these incentives.

- They were concerned about the possibility that these incentives might "blur" the line between government and private enterprise. Some of these incentives were perceived by environmental groups as involving EPA too much in the activities of industry.

- Although they were enthusiastic about the biological control incentives, they emphasized that the rigor of EPA's review of these products should not decrease.

PART TWO

FINAL INCENTIVE DISCUSSION PAPERS

INTRODUCTION

In this part of the report, more detailed consideration is given to incentives selected in this program for possible implementation and future evaluation. Nine incentives are discussed:

(1) Increase Availability of Minor Use Pesticides
(2) Increase Utilization of Integrated Pest Management
(3) Decrease Regulatory Hindrances to R&D
(4) Increase Government Support of Basic Research
(5) Increase Information and Training for Users
(6) Lengthen Patent Life
(7) Improve Communication Between Pesticide Industry and EPA
(8) Advertise Safety on Product Label
(9) Reduce the Risk of Product Development by Industry

Many of these so-called incentives actually include several individual actions, each of which might be considered to be an incentive for increased R&D of pesticides, that address the same problem. It is expected that several, if not all, of these incentive ideas might be implemented in order to achieve the desired results.

Each incentive description includes the following topics:

A. Problems Addressed
B. Background
C. Specific Incentives
D. Possible Results and Impacts
E. Summary Outlook

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INCENTIVE 1. INCREASE AVAILABILITY OF MINOR USE PESTICIDES*

A. PROBLEMS ADDRESSED

A pesticide use is considered minor if its market potential is insufficient to justify the anticipated registration costs and other marketing expenses on the part of the registrant or manufacturer. These may include uses for agricultural crops, as well as for ornamentals, forest products, and waterways. At the present time, there are no control methods available for some of these pest problems.

The problem with clearing registration of these uses has been magnified in the past few years for a number of reasons. Primarily, the producers feel that testing costs are so great that registration of minor use products is no longer worthwhile. The high cash value of some minor crops (such as strawberries or wild rice) may also prevent producers from registering products because of liability concerns. In addition, the avenue of state registration may not be as available for these uses as it once was. The new legislation has had an impact on the user as well, prohibiting "use inconsistent with the label." Thus many means of providing a pesticide or pest control method for a minor use have been eliminated, at least temporarily, and have resulted in the lack of pest control methods for minor uses, which is the problem addressed by this incentive.

B. BACKGROUND

(1) Agency Involvement

Several government agencies have attempted to increase the availability of pesticides for minor uses.

- IR-4. The IR-4 project was initiated in 1963. This organization, which is now funded by USDA ($500,000 in 1976), acts as a coordinator for State Experimental Stations and regional laboratories, EPA and industry. Each year IR-4 receives a list of requests with priorities indicated, from state liaison and technical representatives. Last year, for example, the IR-4 staff screened 2200 requests, 550 of which were pursued. These requests are reviewed further with EPA to determine what kind of information is necessary. The IR-4 staff then approaches the particular company involved to assess the company's willingness to register the product for minor use. Designated Leader Laboratories for the region are contacted, and the regional coordinator arranges the necessary tests. With the test results and other necessary material, IR-4 or the applicant petitions

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*Based in part on preliminary incentives 1 (Insurance for Minor Crops), 7 (Supplemental Funding for IR-4), 9 (Crop Groupings for Minor Crops, and 19 (Insurance for IR-4).

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for a tolerance and for registration.

The IR-4 program has been well received but has had somewhat limited results, obtaining only 40-50 minor use clearances per year. The effort has been hindered in the past by lack of funds, lack of cooperation by some pesticide companies, and difficulties in getting residue work done. Funding is now available through CSRS, and the establishment of Leader Laboratories is improving the coordination of residue work.

- EPA. EPA has taken several steps to alleviate the minor use problem. Prior agreement generally is achieved concerning requirements for minor use requests and the petition fee is waived. Experimental permits often are not required for the testing, but if they are, an abbreviated application form is available.

In addition, some latitude has been shown in relation to Section 12(a)(2)(G) of FIFRA, as amended, (use inconsistent with the label). PEPS (Pesticide Enforcement Policy Statement) II allows use of a pesticide for non-registered use by a PCO (Pest Control Operator) on a structural pest problem. PEPS V considers the use of a registered pesticide for the control of pests not named on the label in agricultural pest control. This vehicle may be used only if the pest-host relationship is improbable, unanticipated, infrequent, or unprecedented in its occurrence, otherwise Section 24c (state registration for special local needs) must be used. This regulation is also expected to help alleviate the problem, and at this time a number of state plans for registering pesticides have been approved by EPA.

In addition, EPA has appointed a Minor Use Officer in the Registration Division, Office of Pesticide Programs. The Minor Use Officer's duties include coordination with IR-4, industry, USDA, and state agricultural experiment stations; he acts almost as a product manager for minor use pesticides.

- USDA. The USDA has also endeavored to solve the minor use problem. As described previously, IR-4 was set up in 1963, and the State Experiment Stations have cooperated by testing many of the requested pesticides.

In 1974, the Office of National Coordinator was established in the Office of the Secretary of the USDA. The coordinator serves as the USDA contact point for EPA and IR-4. The office was originally set up to serve as the collection point for all requests for minor use pesticides. However, this function is still being performed by IR-4.

In 1976, USDA instituted a minor use expansion program. The funding of $150,000 from CSRS supports four regional data collectors and a coordinator in Washington. The data gatherers, with the help of IR-4 liaison representatives, will seek out and question many people concerned with pest control to determine their needs. The purpose of this project is to fill the gaps in the present determination of needs by IR-4, especially for the non-food uses. All of the requests will be funneled to an office in Washington where a "National Needs List" will be compiled. After the interest of industry in registering these products has been determined, the needs list will be turned over to IR-4. This program is now funded as a short-term project, expected to take about one year.

Two purposes are behind the institution of this project. First, USDA is attempting to determine accurately the magnitude of the minor use problem. Second, with this information, EPA and USDA, including IR-4, will be able to assess their abilities to deal with the problem and the needs for expansion of the respective offices.

(2) Minor Use Proposals

Many programs have been proposed to help alleviate the minor use problem; however, few have had much success.

- Crop groupings. Some crop groupings exist for non-systemic pesticides and for obtaining negligible tolerances.

In 1962, 27 groups were established for various crops for the purpose of obtaining tolerances for non-systemic pesticides. The requirements are not specific: "it may be possible to make a reliable estimate of the residues to be expected on each commodity in a group of related commodities on the basis of less data than would be required for each commodity in the group, considered separately."[*]

In 1967, crop groupings were instituted for establishing tolerances for negligible residues. In this scheme, data for a representative number of crops are sufficient for setting a tolerance for the group. These groupings, although helpful, are somewhat limited.

Duggan and Duggan conducted a comprehensive study in 1973 to develop food classes for pesticide residue group tolerances. Ten major food classes contained 33 groups suitable for pesticide tolerances. These groups in turn contain several "primary" crops, and a number of "secondary" crops. For the establishment of a group tolerance, detailed information for registration and tolerance setting must be available on the primary crops and, in some cases, one or two of the secondary crops.[**] Although this proposal could aid the setting of tolerances for minor crops, it would not provide for minor uses on major crops. In addition,

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[*] FR. Dec. 5, 1962, 12093

[**] Duggan, Reo E. and M. Bonner Duggan, Study to Develop Food Classes for Pesticide Residue Group Tolerances, Contract No. 68-01-0774, Office of Pesticides, U.S. Environmental Protection Agency, Washington, D.C., 1976.

EPA felt that Duggan did not consider the different ways the same pesticide would be used on members of a group. As a result of these and other problems, EPA rejected this proposal.

Martin Rogoff of OPP's Registration Division developed a system of extending pesticide tolerances on the basis of "allowable daily intakes." This proposal has not been acted upon because the EPA Science Advisory Board feels a thorough review of EPA's tolerance setting procedure is necessary before any action can be taken.

More recently, Dr. C. C. Compton of the IR-4 project has proposed a grouping plan for ornamentals. EPA is in the process of implementing this plan, although in a somewhat modified form.

- Reorganization and/or coordination. In 1975, EPA proposed a plan for the registration of pesticides for minor uses utilizing available resources at EPA, USDA and IR-4. Under this plan, the minor use needs would originate at the state level as they have in the past; however, the requests would be transferred to a regional USDA coordinator who would review them for accuracy and gaps. The regional coordinator would also collect any information already available in the region and submit the package to the National Coordinator. In the past, IR-4 has received numerous incomplete requests, and this proposal is intended to take some of the burden off that office.

The National Coordinator in cooperation with EPA liaison staff would determine if the product or any substitutes had been registered and whether additional data were available from other sources. After this review, the package would be sent to EPA for classification by the Minor Use Officer and Science Officer of the Registration Division as follows:

1. Additional data not required. The coordinator will then contact industry to determine their interest in registering.

2. Additional data is required--minor.

3. Additional data required--major. The National Coordinator will contact industry concerning their interest in requests in both Category 2 and 3. If they agree, the package is turned over to IR-4, who, through their Leader Laboratories, arranges the tests, obtains the tolerance; and then provides the data to industry.

4. Cannot be registered (suspect chemical, cancelled pesticides)--the National Coordinator will suggest substitutes to the Regional Coordinator.

However, this program in its entirety and fully implemented would require a good deal of cooperation between EPA and USDA. As a result, the plan as a whole has not been instituted and, as of now, IR-4 is still carrying much of the responsibility.

- Liability. Industry seems reluctant to register products for minor uses because of possible liability. To date, no proposal has been presented to deal directly with this problem.

C. SPECIFIC INCENTIVES*

Three major actions are proposed:

- Increase the efficiency (number of products registered) of IR-4. Since IR-4 appears to work well, no new agency or group is needed. However, the efficiency of handling the requests should be increased, and the initiation of the EPA-1975 plan drawn up by Fowler and Baker would do this by instituting a screening process at the regional and national levels, and at EPA, all before the requests reach IR-4. The plan also frees IR-4 from its contacts with industry so it can concentrate on getting the residue work done. (More personnel at the IR-4 project office at Rutgers are also necessary to increase the number of clearances.) Efficiency would also be increased by a better determination of needs in the United States. This approach is embodied in the USDA plan for regional data gatherers.

- Devise and institute a crop grouping plan, designed to include minor crops.

- Initiate a survey or other effort to determine the need for a program to deal with liability.

These three steps are all closely related; however, the implementation procedures are quite different.

(1) Increase the Efficiency of IR-4

The USDA plan for Regional Data Gatherers is an attempt to determine the magnitude of needs for minor use pesticides. Since the results of this project may have some bearing on any kind of national program for minor use, it seems reasonable to wait until the results are in to set up such a program. The EPA plan of 1975 started out well, and the reasons for its failure are unclear; there appears to have been a basic conflict between USDA-ARS and EPA, and the task force that set up this program is now dissolved. The USDA staff feels that they are well aware of the need for a national program and has undertaken such a program on its own in the regional data gatherers. EPA staff were asked to cooperate, but declined, feeling that USDA had rejected their national program and that the data gatherers addressed only a small part of the overall problem.

There will obviously be some difficulty in setting up a national program for minor uses, and some compromises will be necessary. The EPA plan of 1975 was an attempt at compromise, however unsuccessful. Although the National Coordinator, IR-4, and EPA played large roles in this plan, State Experiment Stations and regional representatives were also crucial to its success.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

As a result of the investigations in this study, the following steps are suggested:

- Prepare the "National Needs List" as planned.
- Regroup the task force from EPA and USDA to examine the results of the data gatherers.
- Reexamine the EPA plan of 1975 in light of the findings and alter it as necessary to better solve the deficiencies evident.

The requirement for the success of these three steps is effective interaction between EPA and USDA. Since no plan is definite yet, it is impossible to predict the precise requirements, results, or impacts of it. It is hoped that any program developed or revised will allow IR-4 to be more effective.

(2) Crop Groupings

The grouping plan for ornamentals by Dr. Compton of IR-4 has had favorable reactions from EPA. In 1976, one chemical has been reviewed and the company involved is going to apply for an amendment to its label to add the new uses included in the groupings. This plan is going to be implemented chemical-by-chemical for about 20 products. Since this project has been successful, it seems possible that an acceptable crop grouping plan could be devised to include minor crops. The reasons for the rejection of the Duggan proposal by EPA are unclear. EPA's basic concern is probably that scientific questions about tolerance setting need to be resolved before the institution of any crop groupings. However, these questions are very complex and will not be resolved for years and would seem to be very useful in the meantime. The following steps are suggested:

- Establish crop groupings. EPA would set up or contract a group of people to develop such a plan and make it compatible with the regulations. It is likely that the crop groupings would at least be based on the Duggan report. The plan will have to delineate what kind of data would be necessary for each crop to obtain a tolerance and registration.

- Establish group tolerances using existing tolerances which agree. The implementation of the crop groupings is not simple. Duggan and Duggan reviewed tolerances to determine multiple tolerances presently on crops within a group. Their review showed that group tolerances could be established immediately for 20 of 56 pesticide chemicals under existing tolerances. Additional crops not previously registered for the use could be included in the tolerance presumably with some residue data. These additional uses could be registered with some data on phytotoxicity. These data requirements would be stated specifically in the crop grouping plan.

- Rectify multiple tolerances. Some of these may have to be left as exceptions, with the group tolerance probably set at the majority tolerance. In some cases, companies may be willing to review these tolerances to make them consistent. It is not clear yet how these differences will be reconciled.

The Duggan report proposed that the groupings would be enacted through publication in the Federal Register as a Statement of Policy. It also suggests that Title 40, Chapter 1, Subchapter E, Part 180 (describing allowable pesticide residues in food crops), will have to be revised.

The requirements for the success of this incentive are not complicated. Basically, the plan developed must be acceptable to EPA. The Duggan report is a good start towards a viable plan, but testing requirements for each pesticide must be determined. EPA's favorable reactions to the grouping of ornamentals suggest an optimistic outlook for this incentive. In addition, comments from 13 people in various positions at EPA were all favorable. However, some parties at EPA are not in favor of crop groupings. The Science Advisory Board, for example, has indicated that it will not be favorable to crop groupings until the tolerance-setting procedure has been reviewed.

Other parties involved are IR-4 and pesticide companies. IR-4 staff are interested in this incentive and have stated that it will be quite beneficial to their activities.

Industry also appears to be favorable towards this incentive. Representatives of six out of eleven pesticide companies who commented on this incentive were positive about it, most feeling that it was feasible and would facilitate registration for minor crops. Five of these companies gave indications of being cooperative in the establishment of crop groupings. One company did not want any of its products used on crops it had not tested. However, a small amount of testing probably would be required.

Crop groupings developed by the Food and Drug Administration before the existence of IR-4 were not utilized extensively by industry. However, the high costs involved with development and registration of pesticides would probably make crop groupings more attractive now.

D. POSSIBLE RESULTS AND IMPACTS

The impacts of this incentive could be quite broad. The development of a crop grouping plan would probably take at least a year. This time would represent a cost to EPA, either for its own staff or directly through an outside contract. Hopefully, the plan could be implemented within 1 1/2 years. At this time new pesticides could fit into this plan immediately, as well as presently registered chemicals that are consistent within the group and for which there are adequate data. Longer-term changes would be recodification of Part 180, especially Subpart C, and the review of multiple tolerances within a group.

Once the plan had been set in operation, several parties would benefit. The work load of EPA reviewers would be reduced, or at least the review would become more efficient. IR-4 would be better able to meet its goals of providing pesticides to farmers for minor crops. Reduced costs of registering many pesticide uses would make pesticide companies more willing to register products for minor uses.

The costs of this incentive would be primarily borne by EPA in the initial stages. There may be some cost to industry in label changes and the amendment of tolerances. Any such costs, however, should be small in comparison to the benefits gained from utilizing crop groupings.

Liability has been discussed as a barrier to the development of pesticides for minor use. However, discussions with industry failed to clarify the magnitude of the problem, for which no solutions are readily apparent. Therefore, it is premature to develop any solutions to this possible problem.

E. SUMMARY OUTLOOK

The institution of a national program for minor uses is not likely in the next year or so. After that time, the situation may improve, but is highly dependent on the relationship between EPA and USDA. This program cannot be set up in any meaningful way without the interaction of these two agencies.

The outlook for crop groupings is much brighter and it is hoped that EPA will establish a group to achieve this goal in the near future. Although there are many scientific questions to be answered about tolerance setting, the benefits of this program could be realized many years before these questions are answered.

INCENTIVE 2. INCREASE UTILIZATION OF INTEGRATED PEST MANAGEMENT*

A. PROBLEMS ADDRESSED

The science of agricultural pest control has been expanded significantly during this century and enabled U.S. farmers to increase greatly their productivity. Current U.S. pest control practices:

- rely preliminantly upon synthetic pesticides for pest suppression;
- apply pesticides according to "cookbook" rules; and
- use cultural control techniques to a limited degree.

Although these practices have increased agricultural production, they have also been responsible for or contributed to the:

- neglect of other, sometimes more appropriate, tools of pest control;
- application of unnecessarily high dosages of pesticides;
- suppression of beneficial as well as destructive species;
- development of pest resistance to certain pesticides; and
- buildup of secondary pest populations.

This incentive seeks to promote the expansion of knowledge about and the increased implementation of Integrated Pest Management (IPM) techniques (which includes the use of pesticides as one pest management tool) that minimize the undesirable environmental and ecological effects of the above phenomena and also control pests effectively and economically.

Since the phrase "Integrated Pest Management" conjures up different impressions to different people, a definition of what is meant by this term is essential. The definition of IPM used here is that set forth by the Council on Environmental Quality:

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*Based upon preliminary incentives 11 (Government Support to Users of a USDA IPM Service), 38 (Federal Marketing of Pest Control Approaches), and 60 (Expansion of the Number and Role of Independent Pest Management Consultants).

> "Integrated pest management is an approach that employs a combination of techniques to control the wide variety of potential pests that may threaten crops. It involves maximum reliance on natural pest population controls, along with a combination of techniques that may contribute to suppression--cultural methods, pest-specific diseases, resistant crop varieties, sterile insects, attractants, augmentation of parasites or predators, or chemical pesticides as needed. A pest management system is not simply biological control or the use of any single technique. Rather, it is an integrated and comprehensive approach to the use of various control methods that takes into account the role of all kinds of pests in their environment, possible interrelationships among the pests, and other factors."*

The practical elements of a functional IPM program, as defined here, include at least the following:

- Regular monitoring of the infestation level of pest species and beneficial species through field scouting or related methods;
- Estimation of when the economic threshold level for a given crop/pest species/beneficial species complex has been reached or is likely to be reached; and
- Suppression of the pest(s) by the most appropriate tool or the proper combination of several tools at the most appropriate time, if the pest infestation level is expected to exceed the economic threshold level.

While many scientists believe that the IPM approach has the potential to minimize significantly the detrimental effects caused by current pest control practices, many changes must be initiated and much energy must be expended before the full potential of IPM will be realized. This incentive addresses ways of overcoming present obstacles and suggests means of encouraging the fullest development of IPM.

B. BACKGROUND

(1) Historical Overview of Pest Control

Pest control has been a necessity for as long as man has cultivated food crops. For centuries, however, all attempts at pest control were physical or cultural--hoeing weeds, burning crop residues after harvest, crop rotation, and plowing. Eventually chemicals--such as Bordeau mixture, arsenic compounds, and lime-sulfur--were discovered to have pest-controlling properties. Follwoing World War II, newer, more powerful synthetic chemicals such as DDT, BHC, and 2,4-D were developed which proved to be of exceptional value in controlling agricultural pests. The development of these and other compounds marked the beginning of a significant new era in pest control--heavy reliance upon chemical means of control.

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*Integrated Pest Management, Council on Environmental Quality, November 1972, page 9.

Very quickly pesticides became recognized as a powerful and reliable tool for the management of agricultural pests. In many situations they became the most effective, dependable, and economical method available to the farmer for controlling bothersome insects, weeds, or plant pathogens. Often no other tool of pest suppression could be implemented as quickly or as easily. In fact, the use of pesticides is currently the only effective control measure for some important agricultural pests. Consequently, some of the long-established cultural practices have been largely or totally abandoned. However, evidence has gradually been accumulated to show that excessive reliance upon chemical control methods has secondary and tertiary repercussions that are detrimental to a sound ecological balance and a healthy environment.

(2) Evolution of Integrated Pest Management

Other methods of pest control--such as development of pest-resistant crop varieties, augmentation of natural enemies, and use of insect attractants and repellants and growth regulators--have been investigated for decades. However, the idea of regular monitoring of pests for the purpose of recommending the most appropriate combination of control techniques, first received widespread attention in the 1960's. The idea gained momentum with the initiation of government-funded pilot pest management projects in 1971. These programs, funded in part by the USDA and in part by the CES sought to transfer to the grower available technology which would "establish multiple and alternative choice systems of pest control that are effective, economical, and environmentally sound." This entire program has grown from two projects in 1971 (one on tobacco in North Carolina and one on cotton in Arizona) to 30 projects in 29 states on 15 crops.

During the first year of a pilot project, the costs of field scouting are completely subsidized by the sponsoring agencies; the grower pays only the cost of pest suppression. Over the next few years the farmer gradually assumes a larger portion of the scouting costs. For the duration of the project, personnel of the local Agricultural Experiment Station and Cooperative Extension Service recommend the most appropriate pest control strategy based on the infestation levels of both harmful and beneficial pests as determined by the field scouts. After 3 to 6 years, each pilot project is expected to become economically self-sustaining with private pest management consulting firms or grower associations providing the scouting and consulting services for a fee. If a project is not capable of become self-sufficient, it is discontinued by the USDA/CES.

(3) Current Status of IPM

Most pilot pest management projects sponsored by the USDA/CES have thus far been primarily "prescription insecticide programs" rather than integrated pest management programs.* Much less effort has been devoted to controlling weeds and plant disease. Furthermore, most pilot projects still rely predominantly upon chemical pesticides for pest suppression although more judicious use of these compounds is usually recommended. Thus, the scope and methods of control used in the most so-called IPM projects are relatively simple.

The limited scope and approach in these pilot projects is partially due to the fact that virtually all basic research in pest control has been pursued along disciplinary lines. The structures of the State Experiment Stations (SES) and the Agricultural Research Service (ARS) of the USDA have reflected the structure of the Colleges of Agriculture which emphasize the disciplinary approach to knowledge. Typically, scholars in these institutions work either independently or in small clusters within the bounds of entomology, weed science, plant pathology, agronomy, soil science, agricultural engineering, and agricultural economics. Interchange among experts from different disciplines appears to be less than optimal. Efforts to the contrary not withstanding, the aim of the SES and the ARS frequently appears to be basic rather than applied pest control research. Rarely in any of these institutions is an ad hoc "mission-oriented" task force formed by experts from several disciplines for the purpose of solving a very specific pest control problem encountered by a group of farmers.

The quality of basic research within the various pest control disciplines has generally been of a high caliber. The scientific research conducted by the USDA and the Land Grant University System has greatly increased our understanding of the life cycle of destructive and beneficial insects, the nature of plant disease, and the botanical functioning of weeds. Much of this knowledge has been utilized to develop more effective pesticides. Although lack of communication and coordination have kept some of this knowledge from being utilized optimally by U.S. farmers, the fact remains that the caliber of basic research in entomology, weed science, and plant pathology is outstanding.

For the most part, newer concepts of pest management have been spread primarily through pilot tests projects. Many of these projects have been highly successful in providing effective pest control, in reducing unnecessary pesticide usage, and in improving per-acre net returns to the grower. In many cases, farmers adjacent to a new pilot project have subsequently begun to use field scouting in an attempt to lower pesticide costs and improve profits. However, in view of the sheer size of the potential market, pilot projects are an inherently limited means of propagating these concepts of pest management.

At present there is virtually no regional or national promotional campaign to arouse user demand for Integrated Pest Management (or prescription insecticide programs) in a similar manner to the advertising used to sell other goods and services to farmers. The U.S. pesticide industry spends millions of dollars in advertising each year in an attempt to influence farmers' decisions about pest control products. Although commercial pest management consulting firms have recently been established, none of them is large enough to finance a widespread promotional campaign for IPM or a prescription pesticide program. Because of the extremely unequal expenditures for promotion spent by the fledgling pest management consulting industry and the well-established pesticide manufacturing industry, newer concepts of pest management face a difficult struggle competing with conventional pesticide usage.

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*At the Conference on Developing Incentives for Pest Control Methods it was recommended that the term "prescription" be changed to "corrective" so as to eliminate any possible legal connotations and suggest the provision of advice on alternative methods rather than specification of specific pest control methods. The authors agreed with this change but have not reworded this incentive paper.

Efforts to implement newer concepts of pest management could be more successful with more effective coordination. One reason for the ineffective coordination is the disciplinary fragmentation of scientific research and the resistance to modifying that approach. Another is the slow dissemination of results from field tests for evaluation and subsequent program modification as needed.

Admittedly the ideal of Integrated Pest Management is difficult to achieve because of the incredible complexity of ecosystems. But the best method of approximating is through greater interdisciplinary effort and more timely response to newly developed information.

C. SPECIFIC INCENTIVES*

(1) Objectives of Incentives

The current prescription insecticide programs are a marked improvement over the typical "cookbook rules" for the application of pesticides. The Integrated Pest Management incentives outlined below are designed to build upon and progress beyond the knowledge and experience developed to date through these prescription programs. The actions identified below have three overall objectives:

- To spread the current prescription pesticide programs as widely as possible;
- To investigate the obstacles which inhibit the integration of numerous techniques of pest suppression; and
- To gradually incorporate other methods of pest suppression as obstacles are overcome and experience is gained.

The presumptions underlying the incentive strategy are that: (1) changing grower practices from excessive application of pesticides to a more judicious use of them is an obtainable short-term goal; and (2) optimum integration of many techniques of pest control will require more time and a better understanding of the difficulties of this approach.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

(2) Propagating Prescription Pesticide Programs

Although the current version of the pilot pest management program has much room for growth, the accomplishments of these projects have been very worthwhile in both economic and ecological terms. Thus, the current program should be continued and expanded to more growing areas, crops, pest species, etc. In order to accomplish this objective, the following actions are proposed.

- Allocate additional federal funds to increase the number of pilot projects. The USDA now is allocating approximately $3 million and cooperating State Extension Services are donating around $1 million annually for the support of pilot pest management projects. All evidence indicates that these funds have been used wisely, and are producing significant results. A 50-100% increase in funding for these projects would significantly increase the number of grower participants in these projects. The EPA should consider allocating part of its budget to the USDA for the purpose of spreading the projects to other growing areas, crops, pest species, etc. Scientists in the USDA and the Land Grant University System should make final decisions regarding which crops/pest species are most appropriate for subsequent experimentation.

- Use generic advertising at the termination of a successful pilot project. Under the current program, successful pilot projects are expected to survive eventually without public funds. Typically, private pest management consultants and/or grower associations are formed to perform the services originally provided by the project. Growers then pay the entire cost of field scouting, as well as the cost of pest suppression. At the termination of the pilot project, public funding of generic advertising on local radio and TV is proposed in order to explain the benefits of field scouting and prescription pesticide application. At the conclusion of a successful pilot project, generic advertising of this type would greatly increase the number of participating farmers in subsequent years.

- Offer a seminar for farmers each autumn to review the season's test results. The Cooperative Extension Service responsible for each pilot project should quickly analyze the results of each year's experience and present its findings to a conference of all participating and interested non-participating growers. A seminar of this type will serve to heighten the participating growers' sense of involvement and increase their understanding of the successes and potential difficulties of the project. It will also excite interest among non-participating growers who may sign up to participate in the succeeding growing season.

- Publish project results on a timely basis for dissemination to growers in other regions. In preparation for the conference mentioned above, the State Extension Service should publish the results and findings of each season's experience. This summary should also be distributed to pilot projects in other areas that are experimenting with the same crops or the same pest species. This exchange of information would broaden the understanding of participating growers and Extension workers in other parts of the country. These printed results also could be used to generate interest in these control techniques among non-participating growers.

- Prepare audio-visual aids to explain the benefits of prescription pesticide application. Based upon the experience of well-established programs (or newly initiated pilot projects), audio-visual aids should be developed to document the economic and ecological advantages of prescription pesticide programs. Movies, film-strips or other appropriate media could then be used by State Extension Service personnel to develop interest among growers for a new pilot project, or by newly formed pest management consulting firms to demonstrate the benefit of their services. The individual State Extension Services would be the most appropriate agency to direct the development of such materials with funds from the state or federal governments.

Prescription pesticide programs are a major improvement over more typical pesticide application practices. The above actions are designed to further encourage the use of pesticides only when needed and only to the extent needed. Every effort should be made to spread this concept as quickly as possible.

(3) Investigation of Obstacles Preventing Integration of Techniques

While many of the likely obstacles inhibiting the integration of several pest control techniques can be identified, considerably more information is necessary about most of them. For each possible obstacle much more needs to be known about the extent to which each obstacle inhibits IPM. Some of the obstacles to integrated techniques are as follows:

- Insufficient scientific knowledge. For some crop/pest complexes, not enough is known about the interrelationships within the agroecosystem to permit commercial experimentation with several techniques. For some pests, pesticides are the only known means of control. To assist in setting research priorities and budgets, a review of the knowledge gaps is essential. As a result, a scope of work should be carefully defined so cooperating scientists can most efficiently pursue the answers to basic scientific questions.

- Ease of pesticide application. In some cases, sufficient knowledge already exists; however, growers still rely primarily on pesticides because of their ease of application. Much more needs to be known about the extent to which ease of application affects decisions of growers. In determining the extent to which the convenience factor influences farmers, much could be learned about possible ways of overcoming this obstacle.

- Speed of pesticide action. One of the advantages of pesticides is the short time required to suppress a pest species. Again, little is known about how influential this factor is in determining pest control practices. If it is a major factor in grower decisionmaking, more attention must be paid to demonstrating to farmers that field scouting provides an early enough warning to permit slower control techniques to be used.

- Reliability of pesticide control. Although more recently the occasional resistance of pest species to certain compounds has tarnished the reliability of pesticides, for the most part, pesticides have demonstrated a remarkable consistency of control. Since farmers are already heavy risk bearers (most notably with regard to weather and market prices), most of them are eager to reduce the risk from pest damage. The desire to minimize this risk has caused some farmers to use pesticides as an "insurance policy." Consequently, pesticides are sometimes applied when they are unnecessary and uneconomical. The full extent of this practice is not known, and a better understanding of it will yield better ways of combating this excess.

- Grower ignorance of pesticide hazard. In some cases, farmers are simply not convinced that excessive pesticide usage poses a potential hazard. To such farmers, the suggestion of more complex methods of pest suppression seems absurd. While farmers are gradually becoming more aware of pesticide hazards, it is critical to know the extent to which farmers remain unconvinced of the potential harm of pesticides.

- The economics of production. In many cases, pesticides remain the cheapest method of control, and it is difficult to provide a sufficiently attractive incentive. However, if more were known about the environmental conditions in which alternative control methods have proven to be more economical, those situations which are similar enough to warrant experimentation with IPM might be exploited.

On the basis of a greater understanding of the most significant obstacles to the integration of numerous techniques, goals and priorities can be determined to best cope with the obstacles. Only if the nature and magnitude of the problems associated with full implementation of Integrated Pest Management are grasped can its full potential be realized.

(4) Incorporating Other Methods of Suppression

Pilot pest management projects are now discontinued after several years, either because they are unsuccessful or because they are successful enough to be continued on a commercial basis with farmers paying the full cost of all necessary services. When scientists believe several control techniques can be integrated for reliable, economical, and ecological control of pests, we propose that new pilot projects be started. They should enlist the support of growers who are already applying prescription pesticides and who were part of a pilot project initiating prescription pesticide application. These growers are likely to be more progressive and consequently more receptive to experimenting with a variety of techniques.

Because of the complexity of successfully integrating several techniques, these more sophisticated pilot projects should be initiated only with a reasonable degree of assurance that success is likely. Several unsuccessful projects may seriously retard grower acceptance of more complex methods of control.

This incentive suggests that the pilot projects become an ad hoc, but iterative, mechanism used by the USDA/CES to introduce new and better methods of pest control on the grower level. Ecologically sound pest control methods are likely to become more complex, rather than less complex. Thus, something more sophisticated than a pesticide container label is required to introduce future techniques of pest control.

D. POSSIBLE RESULTS AND IMPACTS

Although it is impossible to predict in great detail or with great accuracy the future impact of the proposed incentive actions, it is possible to describe in broad outline some of the more likely effects if the above recommendations are implemented successfully:

- Within five years as many as 10 million acres could be treated with pesticides on a prescription basis rather than a "cookbook" basis.
- Within ten years 30-50 million acres could be treated on a prescription basis.
- The proper goals and strategy for the full implementation of IPM will be understood much better.
- Five years from now only a few pilot projects will approach full implementation of Integrated Pest Management.
- The pest management consulting industry will grow rapidly over the next several decades.
- In ten years pesticide residues in the environment in some areas in which pesticide application has historically been excessive will decline discernibly.

E. REQUIREMENTS FOR SUCCESS

Some of the more concrete requirements of these incentive actions are:

- Commitment of funds over a long time frame for additional pilot projects, generic advertising, and further scientific research.
- Acceptance by EPA that its role in this project is advisory.
- Increased ability of the USDA and CES to explore other methods of pest control.

F. SUMMARY OUTLOOK

The outlook for the widespread implementation of prescription pesticide application practices is excellent. This concept has been successfully practiced in enough diverse agricultural situations to warrant the belief that the idea is practical and economical. This is the most feasible initial step toward the full implementation of Integrated Pest Management. Within another decade this first step may become common practice among U.S. farmers. However, the complete implementation of Integrated Pest Management will require much more time and effort. Indeed its future is not as certain since there has been little opportunity to evaluate the economic viability of IPM. Even if IPM is or can become economically competitive with current pest control practices, its implementation on a commercial basis on a majority of U.S. cultivated acreage is not likely to occur before the turn of the century.

INCENTIVE 3. DECREASE REGULATORY HINDRANCES TO R&D*

A. PROBLEMS ADDRESSED

Among the objectives of the incentives program is the goal of alleviating the problems caused by the regulatory activities of EPA. The specific regulatory activities under discussion here are primarily those contained in Section 3 of FIFRA, as amended, which requires that pesticides be registered after a review by EPA before they can be used. It gives EPA the power to register or not to register a pesticide, to restrict usage of pesticides, and to require a pesticide to be reregistered every five years.

The decisions involved in this Section are based on a set of tests required to be performed and submitted by the registrant for review by EPA. The tests are designed to assess the potential acute and chronic toxicity of the pesticide to man and to non-target species, as well as to assess the effectivenese of the pesticide.

As discussed earlier, the implementation of Section 3 is expected to act as a barrier to pesticide R&D; the incentive described below is designed to reduce some of the specific regulatory hindrances that make up such a barrier. The identification of these hindrances is based primarily on comments received from the pesticide industry. These comments may be mere complaints, or attempts to "shout down" some regulatory requirements; or they may be justifiable and valid. Because the decision whether or not to invest in pesticide R&D is a complex one involving many other factors besides regulatory requirements, it is almost impossible to isolate the effect of regulatory requirements. For this reason, EPA should not attempt to determine the validity of industry complaints either on the basis of Section 3 as a whole or on the basis of specific registration activities or requirements.

This lack of a means for validating complaints, however, should neither cause EPA to act on all complaints nor cause it to dismiss them entirely. Instead, as a compromise, the complaints should be screened for coincidence with EPA's own interests. The set of incentive actions described herein resulted from such a screen, i.e., they suggest improvements which, although addressing industry complaints, can be made solely in the interest of making the Office of Pesticide Programs a more efficient, open, scientifically competent, and cost-effective regulatory program. It should be noted that OPP has already made great progress in this area and its attitude toward continued improvement is reflected in its involvement in this incentive program.

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*Based in part upon preliminary incentives 16 (Reduced Registration Time for Safe Products), 17 (Facilitate Registration Process for Innovative Products), 18 (Reduced Registration Requirements for Biological Controls), 19 (Decreased Uncertainties of Registration Process for Applicants), and 20 (Reduced Time and Cost of the Registration Process).

The incentive below then presents a series of suggested actions that will improve the cost-effectiveness of the regulatory activities at OPP, as well as address some industry grievances. This incentive is meant to be a shopping list of actions from which OPP decisionmakers, after discussions with those involved, can choose the set of changes they feel can do the most good with the least depletion of resources or deviation from legislative intent. Such a selection must result in a critical level of change, i.e., a significant decrease in time requirements, cost, and uncertainties, etc., resulting from these actions. It is not the number of changes that matters but rather a multi-faceted approach; that is, some change should be made in each of the following areas addressed by this incentive:

- The time (and therefore the cost) involved in EPA's review of registration applications,
- The time and costs required to conduct the tests themselves prior to submittal of a registration, and
- The difficulty in making R&D decisions because of uncertainty about current and future Section 3 regulatory activities.

Each of these is discussed separately below, in terms of the previous attempts to solve the problem, possible results and impacts, and requirements for success.

B. DECREASING THE TIME AND COSTS OF REGISTRATION REVIEWS*

(1) Background

Much effort has already been made within EPA to reduce the time required to review a registration application. Most of these changes have been administrative: the product manager system has been instituted to expedite the administrative flow of an application and to provide a focal point for interaction with the applicant; the reviewability evaluation team has been established to make sure only fully completed applications are reviewed; administrative personnel have been increased in the past few years to about 125 in the Registration Division (compared with about 75 scientists). Significant improvements have resulted from these changes. About three years ago, the average time for application review (from receipt to final decision) was 289 days, including the time that the applicant took to obtain and submit any new information requested. The average is now down to 166 days. "Cycles" of requesting additional information and reviewing this information have been reduced from 3.8 cycles per application to 2.2.

While these changes have brought improvements, they also have raised a number of issues involving the conflict between the efficiency of the review and the scientific thoroughness of the review. These opposing interests are manifested in the interaction not only between industry and EPA, but also between the managers and the scientists within the Registration Division itself, and recently between members of Congress. On the one hand, congressional inquiries concerning the delays in the review of a constituent's application are fairly common. Lately, on the other hand, a congressional committee has also become concerned about the possible 'assembly line' nature of the review process and has begun to investigate the validity of the scientific data that has been passed through the registration review. In order to ensure scientific validity of registration data, the data submitted may be subject, in the future, to "auditing," i.e., a random check of the raw data and test conditions.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

The issue of whether or not to give priority to safer, innovative, or otherwise more favorable products has also arisen as part of recent efforts to improve the registration process. On the one hand there is a desire to give quicker service to these applications as an incentive for their development; on the other hand, it is felt that these products should not receive favored treatment and possibly a less thorough review. The basic conflict is: should EPA take applications on a first come, first served basis, giving each equal attention without bias, or should it use the registration process as a mechanism to encourage continued interest in certain types of products? Currently, EPA has decided that it will give priority to registrations that fulfill the unmet needs of minor crops, but not to any other group of products.

(2) Specific Incentives

- The number of scientists available to review applications should be examined in order to determine whether additional scientists could significantly decrease the review time. The time an application spends in each of the scientific review branches (e.g., toxicology, chemistry) should be established, and any 'bottleneck' branches should receive added attention when the number of positions to be allotted next year is determined. Furthermore, if data auditing is instituted, additional scientists will have to be hired for that purpose.

- Scientific reviewers should become more knowledgeable about agriculture and pesticide usage. This would help ensure that any request for additional data will be relevant to the potential use circumstances of the pesticide. This increased knowledge could be acquired through seminars given by pesticide companies and pesticide user groups. Training by USDA might foster a spirit of cooperation between the two agencies. (This incentive action is an example of the small effort needed to improve significantly EPA-industry/agriculture relations.)

- Mechanisms should be developed to notify an applicant that additional information is required. One possible mechanism is the institution of a dual review by two scientists in each of the scientific branches. Initial reviews by a less experienced scientist could enable the applicant to receive early notification of the more easily seen gaps. Any requests for additional information (after the normally required information was reviewed) would be left to a senior scientist. A dual review might appear to lengthen a review process; however, this system is currently practiced in the Chemistry Branch in the Registration Division and it has not slowed the review or become a bottleneck.

- The possible disincentive to the development of biological controls caused by difficulties in getting such products registered should be examined. Companies involved in this development believe reviewers in the Registration Division generally lack expertise concerning biological controls, or have some experience but usually restricted to one or two types (e.g., viruses) or biological controls. The total extent of knowledge in the Registration Division of various types of biological controls should be examined, and if already adequate, the persons with this knowledge should be more clearly identified as being responsible for biological control reviews. If the level of expertise is not adequate, those interested in biological controls or having some familiarity in particular areas, should be trained in the relevant information about the whole range of biological controls, including information on the mechanism of control, patterns of usage, and potential hazards.

(3) Possible Results and Impacts

If a number of the incentive actions described above are implemented, several changes might occur. The incentive review may take less than the current 166-day average. The number of cycles, i.e., the requests for additional data, might decrease, and public and user confidence in the decisionmaking ability of the registration division would increase. The primary cost of implementing these incentives would be financial. Increasing the number of scientists on the staff would require additional funds to be given to the registration division. Funds would also be necessary to implement training programs to increase the reviewers' knowledge of agricultural and pesticide usage, and to train some personnel to become familiar with the various types of biological controls.

C. DECREASING THE TIME AND COST OF TESTING REQUIRED PRIOR TO REGISTRATION

(1) Background

About a year ago the Section 3 Guidelines on the required tests for registration were issued in draft form in the Federal Register. The sum of the costs of the tests (where such information is available) is $500,000. (The actual figure is probably higher since not all costs of the tests are available.) In comparison, putting together the registration application and following it through costs about $30,000. Any incentive, therefore, which seeks to decrease the time and costs of regulatory activities must focus on the tests themselves as the primary source of regulatory costs.

Although consideration may have been given to the time and costs required for each test when the Section 3 Regulations were drafted, no further effort appears to have been directed toward finding cheaper ways to get an equal amount of information relevant to decisionmaking.

Because no previous attempts have been made to address the problem of the time and cost of the tests themselves, the incentive actions which follow are designed to initiate such action: to begin to incorporate consideration of the costs of tests, both for individual products and for pesticides as a whole, into the decisionmaking of those involved in test requirements.

(2) Specific Incentives

- EPA should begin to keep track of the costs of the tests required for individual products. When a company seeks guidance from EPA concerning what tests it should be doing for its particular products, EPA should add up the approximate anticipated costs of such tests. These figures can come from previous studies on the cost of the registration requirements or can be based on information exchanged between the company and EPA. Such a tallying effort would accomplish several purposes:

    1. It would make the EPA reviewer requesting the information conscious of the cost of the test, possibly leading to a quick, mental, cost-benefit check on the part of the requester of the information.

    2. It would give EPA a data base from which to answer complaints from congressmen and companies about the cost of registration requirements.

    3. It would provide the basis for checking the consistency of reviewers in their requests for information.

- EPA should monitor achievements of other federal agencies in the development of cheaper and faster tests for carcinogenicity. Currently, the tests required by EPA involve two-year feeding studies, ranging in cost from about $75,000 to $125,000. The duration of the tests is more crucial than the cost since the two-year time frame requires that they be started early in the development of a pesticide while there is still more uncertainty as to whether the company should go ahead with a product. If new tests become acceptable to and used by other federal agencies, EPA should be ready to substitute new tests for those currently required in the guidelines. It is unlikely that EPA would, or even should, lead the way in adopting these new test procedures.

- Any additions to the tests that are required by the Section 3 regulations should be subject to a cost-benefit review that includes consideration of any available alternative test approaches. EPA should actively seek guidance from other agencies on these alternative approaches.

(3) Possible Results and Impacts

The time and cost of the test requirements for registration would probably decrease gradually over a long time. In terms of the critical thresholds of change mentioned for this entire incentive, this reduction in the time and costs of the tests could represent the largest single agent of change, especially for smaller companies that desire to develop and register new pest control products but for whom the cost of test requirements represents an insurmountable barrier.

(4) Requirements for Success

The major barrier to this set of incentives is EPA's hesitation to reduce the amount of information submitted for review. Yet such a cost-benefit consideration has been included informally in the design of the individual test requirements in the Section 3 regulations (although it appears that less consideration was given to the overall set, or number of the tests). At present incorporating such cost considerations, in individual cases or across the board, is subject to much variability because of the lack of an overall policy on just how much weight cost considerations should have in these decisions. If this incentive is adopted, the establishment of such a guidance policy would be a necessary first step.

D. IMPROVING THE REGULATORY ATMOSPHERE WITHIN WHICH PESTICIDE R&D IS CONDUCTED

(1) Background

Much effort has already been expended to open up the registration process and make it more accessible and more understandable to the user. The product manager approach has been particularly successful in doing this. Yet a remaining perception of the registration process as continually changing (partially in response to industry complaints), causes uncertainty about future changes in the regulatory requirements. Pesticide R&D decisionmakers must anticipate these changes today when deciding whether to go ahead with products that will face registration five or six years from now. Furthermore, in designating funds to be used for R&D, company managers must be able to anticipate the future regulatory environment and the effect it might have on products that result from those R&D funds.

(2) Specific Incentives

- An ombudsman should be appointed within the Registration Division to represent the users of the registration process, i.e., pesticide companies, and deal with their complaints and concerns. Although the product manager approach is, to some extent, based on this idea, the ombudsman would go one step further: he could hear complaints from a number of applicants and, with this overview, suggest changes.

to be made in the registration review system. At the very least he could bring such across-the-board problems to the attention of the head of the Registration Division, absorbing some of the complaints of industry before they reach Congress. Such issues as surrounded the registration application for chlorobenzilate, for instance, might have been resolved within the Registration Division rather than in Congress. This mechanism also could ensure consistent reviews by scientists and product managers, bringing any unfair treatment to the attention of administrators. The authority of this ombudsman to make these grievances heard and to bring about change would need to be clearly defined at the outset.

- Information on "what to expect" should be given to each potential registrant on request. At present the information package that is distributed to the potential registrant is primarily forms and instructions for completing the registration application itself. An information package should be developed that describes the process of registration review, how a decision is made, etc. Additionally, upon receipt of an application, EPA should assess its work load and give the applicant some idea of the time needed to review the application.

- To enable companies to do longer-term planning and to make decisions on products that may go to registration five years from now, EPA should give some assessment of the stability of the present Section 3 Guidelines. EPA should indicate if it is planning a major review of these regulations and possible update within the next five years. On the other hand, if the registration guidelines will probably be changed only as new information becomes available that points out the need for additional tests, this attitude should be made publicly known. Indications given concerning the stability of the Section 3 regulations would not be binding on EPA in any regulatory sense. Instead it would merely give those responsible for making long-term R&D decisions the needed input of EPA's current thinking on future registration requirements.

- EPA should provide some guidance on decisionmaking criteria to help R&D decisionmakers decide whether or not to go ahead with a potential product. To do this, EPA should analyze its past registration, classification, and cancellation decisions and determine in general what it will and will not allow on the market. This should be communicated to pesticide R&D decisionmakers to give them an idea about where they stand with a particular product. This kind of clarification would be especially helpful if it included a description of EPA's balancing of the risks and benefits of a pesticide.

- To help both long-term and short-term planning by companies involved in biological control development, EPA should clarify its position as promoter or non-promoter of these products. There is some confusion within these companies about whether or not EPA will encourage the use and development of biological controls and whether or not they can expect some kind of encouragement by being given priority treatment in the registration process.* As discussed earlier, the issue of whether or not EPA should promote certain types of products, and if so whether this promotion should involve priority treatment within the Registration Division, is a basic conflict within EPA. The unresolved nature of this conflict is felt particularly acutely by companies involved in biological controls; this resolution would significantly decrease the uncertainty in long-range planning by these companies.

(3) Results and Requirements for Success

Decreasing the uncertainty caused by the current implementation of the Section 3 Guidelines would significantly improve the atmosphere in which pesticide R&D is now conducted. It would make long-range planning and justification of R&D funding requests much easier, while at the same time promoting an EPA image of reasonableness in the eyes of Congress and the general public. The major efforts required to implement these actions are administrative (on the part of EPA) and involve clarification of internal expectations and policies.

F. SUMMARY OUTLOOK

Not all of the actions suggested here will be implemented. Hopefully, however, this "list" provides enough of a choice to permit a broad multi-faceted program of action to be implemented that eventually should improve the potential for pesticide R&D in this country. Given an extension of EPA's interest in this incentive program, i.e., to include implementation of these suggestions which have resulted from it, the outlook for reaching a critical threshold of change in the reduction of regulatory hindrances is favorable.

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* It may be that the limits of such a "promotion" would be an elimination of any disincentives inherent in the current review process as discussed in the first part of this incentive.

INCENTIVE 4. INCREASE GOVERNMENT SUPPORT OF BASIC RESEARCH[*]

A. PROBLEMS ADDRESSED

The development of new pesticides requires applied pesticide research. Although industrial organizations are expected to continue to perform the majority of such research, all applied research depends upon fundamental findings which spring from basic research activities. The less traditional the applied research is, the more the need for supporting fundamental data. Thus, there is logic in the expectation that increasing support for basic research may act as an incentive to the successful performance of novel applied research (which may yield novel pesticidal materials). However, inherent in this logic is the assumption that the lack or projected lack of fundamental data is indeed a problem.

Basic research represents the ordered pursuit of new knowledge. It is largely an individual effort without direct institutional consequences. Only by being properly utilized do basic research results become important in the elucidation of novel chemical pathways, the design of synthetic programs by industrial organizations, the development of effective screens for such agents, the devising of efficient test systems to allow registration, and the potentially useful and rational modification of applied research programs. Basic research can never be directed to meet any of these ends. Thus, if the solution of this problem is to have an impact on novel pesticide development, all of the other incentives (existing and potential) which stimulate the performance of goal-directed and productive commercial research must be operational. Basic research results cannot "push" pesticide innovation; they can only assist by decreasing investment or risk in the early stages of the development process.

B. BACKGROUND

(1) Previous Attempts

The "use in basic research of organisms and ecosystems that [illegible] yield benefits to the science of pest control" is supported by a number of agencies. The National Science Foundation (NSF) supports approximately $3 million of extramural research as part of its basic scientific programs. The Department of Health, Education and Welfare (HEW) supports $2 million of fundamental entomological research to enhance basic knowledge and to encourage the application of such knowledge to disease control.

U.S. Department of Agriculture (USDA) funds many programs which have a basic research element. The Hatch Act required Agricultural Experiment Stations to conduct original research bearing on and contributing to the establishment and maintenance of a permanent and effective agricultural industry. An implied objective under the Hatch Act was to maintain resources for training and educating individuals to solve future agricultural problems.

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[*] Based upon preliminary incentive 32 (Government Funding of Basic Research).

USDA funds support botanical and entomological research extramurally and through the Agricultural Research Service (ARS). In 1972, USDA and state Agricultural Experiment Stations spent $627 million for agriculutral research, $132 million of it for pest control research. Of this, $26 million was classified as Target I. Such research is intended "to gain knowledge of the taxonomy, biology, ecology, physiology, pathology, metabolism, and nutrition of pests and host plants and animals" and may appropriately be considered basic.

Finally, the Environmental Protection Agency has recently supported research in accordance with the provisions of FIFRA, as amended, Section 20, which states, "The administrator shall undertake research....and give priority to develop biologically integrated alternatives for pest control." The basic research component of this work is expected to focus on food chains involving insects of economic importance.

A significant body of basic research is now supported by the government. Although the millions of dollars of "relevant" projects cannot be fully isolated from the operating funds of the above agencies, the total approaches $50 million per year. The magnitude of the existing effort is reflected in the size of the academic staffs of the state and land grant colleges, as well as in the proliferation of specialty scientific journals to publish their output.

Given these existing programs, this incentive can have only a qualitative rather than quantitative impact; it can increase the flow of fundamental data but in its absence, a $50-million stream will flow nonetheless. The various agencies already involved have constructed the foundation for this incentive. Its implementation can only build upon what already exists.

(2) Current Issues

Three critical issues impinge directly on this area. The first is the question of how money gets spent. Most funding of basic research now employs a mechanism by which principal investigators receive grant support. Much of this money really funds the growth of institutional laboratories, the purchase of instruments and the training of manpower, rather than the direct extension of the knowledge base. Is this a cost-beneficial means of accomplishing the stated goals?

A second issue is the choice of projects to be funded. The academic approach is to support those research proposals which encompass the most creative scientific hypotheses and means of obtaining new knowledge. Often such funding is allocated irrespective of the biological or chemical model under investigation. Is this the best means to generate data of eventual utility in the development of new pesticides?

A third issue revolves around the funding source. In its report, "Pest Control: An Assessment of Present and Alternative Technologies,"* the Executive Committee of the Environmental Studies Board, National Research Council, National Academy of Science, recommended that "the NSF and other agencies responsible for the support of basic sciences encourage the increased use in basic research of organisms and ecosystems that may yield benefits to the science of pest control; the USDA and other agencies with a pest control mission should also be funded so that they can make competitive extramural grants for basic research to qualified investigators wherever they are located, in order to enlarge the scope and perspective of research dealing with pest control problems." Apparently, a firm distinction is made between the NSF and USDA in their support of basic research. Which agency would have the most impact on pesticide development if given this incentive program as a charter?

(3) Other Background

The role of basic research is often misunderstood. As such this area has not received dynamic support. From 1967 to 1974 government support of basic research in life sciences did not increase (in terms of constant dollars) over that period. In contrast, funding of applied life sciences research experienced as real growth rate of 4%.** A few of the reasons for this are worthy of discussion.

Basic research is generally considered to be research whose purpose is to uncover new knowledge. It is an essential part of a three-part process of innovation, the other two parts being application and development. Successful innovations require balanced effort among these three parts. Too much or too little basic research activity in relation to applied research and development results in wasted effort. While a scarcity of new knowledges makes it difficult for applied research to move ahead as fast as it might, too much new knowledge not applied wastes resources. At present the prevailing sentiment is that we need to emphasize applied research and especially development. The tendency is to solve problems by focusing at the very end of the innovative process and to forget that the beginning may be just as important. It is quite possible that in the present climate society has downgraded basic research in its impatience to solve pressing social issues.

Since basic research is not carried out for immediate gains or application, it is incorrectly considered as being equivalent to a long-term investment in fixed capital, yielding a return a long time in the future. However, basic research yields a flow of information from the present into the future. A key idea can occur at any time, today or perhaps ten years hence. The chief characteristic of the return from basic research is that it is impossible to specify when a key idea will occur; the returns are uncertain but they are neither short nor long term.

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* Pest Control: An Assessment of Present and Alternative Technologies. Volume I. Contemporary Pest Control Practices and Prospects. National Academy of Sciences, Washington, D.C., 1975.

** Shapley, Willis H., Research and Development in the Federal Budget: FY 1977. American Association for the Advancement of Science, Washington, D.C., 1976.

This way of viewing basic research suggests that we cannot neglect to continue the flow of new knowledge even if it is politically expedient to place a high priority on immediate results.

The future is uncertain particularly now when change is occurring so rapidly. Neither scientists nor anyone else can possibly foresee what the key issues will be even only a few years into the future. The danger to the environment and human health caused by chemical pesticides came as a dramatic surprise to most people in the 60's. Many future important problems are bound to come as surprises. If we are to respond to these problems quickly and effectively, an adequate body of knowledge must exist at this time. We can neither predict problems nor foresee which avenues of basic research will develop the new knowledge that will be applicable to these problems.

The rationale for basic research that has been developed over the years is based on a strategy suited to decisionmaking under uncertainty. The strategy is akin to that of a general when he maintains some of his forces in reserve to meet any contingency. Basic research provides a reserve of new knowledge available for any contingency in the future. Obviously, the cost-benefit of maintaining reserves can be appreciated only retrospectively.

C. SPECIFIC INCENTIVES*

(1) Specific Objectives

The EPA, USDA, and/or NSF should fund a program of basic research on insect and plant systems with the exception that information will be gained which will be valuable to the long-range development of new pest control methods. An annual expenditure of $10-25 million for the program would result. The major recipients of the new funds would be academic investigators in the United States and abroad. It is expected that 200 research projects would be initiated resulting in an average "productivity" of 500 research papers per year.

(2) Description

The major pre-implementation step is to resolve the three issues presented under Section B(2). In the course of this study, insufficient input relative to basic research was received to resolve these issues. However, for the prupose of the ensuing discussion the issues will be considered to be resolved as follows:

- Funding will be in the form of grants available to non-profit institutions, including government laboratories.

- Awardees will be selected by peer review committees organized by scientific discipline and including USDA ARS scientific personnel.

- Programs will be administered by the National Science Foundation.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

Implementation steps will easily fit within the NSF's existing structure. The availability of grants for basic research involving "organisms and ecosystems that may yield benefits to the science of pest control" will be announced. Peer review committees will be organized. Funds will be allocated among the committees. Awards will be made. An increased NSF administrative staff will administer the grants.

No formal monitoring process will exist. Rather, the grant renewal process will serve as a means of quality control.

D. POSSIBLE RESULTS AND IMPACT

(1) Results

Depending upon the field in which basic research is conducted, a duality of ends can be envisioned. Comroe and Dripps (Science. 192, 105, 1975) cite a Department of Defense study which concluded that the contributions of university research to military weapons development are minimal. Scientists, according to the study, contribute most effectively when their effort is mission-oriented, and the lag between initial discovery and final application is shortest when the scientists work in areas targeted by a sponsor. If agricultural research is analogous to weapons development, the funding of basic research would be ineffective.

The paper by Comroe and Dripps also provides evidence that in the biomedical area "clinical advance requires different types of research and development and not one to the exclusion of another. Thus, the problem is not either-or, but a question of how much support to one type and how much to another. Our data compel us to conclude that a generous portion of the nation's biomedical research dollars should be used to identify and then to provide long-term support for creative scientists whose main goal is to learn how living organisms function, without regard to the immediate relation of their research to specific human diseases, and that basic research as we have defined it, pays off in terms of key discoveries almost twice as handsomely as other types of research and development combined." If agricultural research is analogous to biomedical research, the funding of basic research can be expected to produce significant results.

In the absence of supporting evidence, a middle ground is taken here. Research would probably flourish under this program, producing new fundamental data. However, little of this fundamental data is expected to have a major role in the development of novel commercial pesticides in the next decade. The most optimistic estimate of the time required for diffusion of basic research findings is contained in a report prepared this year for the NSF Science and Technology Policy Office by the New York State College of Agriculture and Life Sciences at Cornell. In this report, it is stated that the results of newly supported basic research on pest and pesticide toxicology "with proper selection of study areas....may have an important impact on pesticide development within a three to five year period."

(2) Impacts

The short-term costs of this program are minor. The sum of $10-25 million will cover both the administrative costs and operating costs of the program. Other costs such as an increased friction between USDA and NSF should be minor.

Unfortunately, the benefits to be expected from this incentive action are also minor. Previous work for ETIP and the results of interviews in this program indicate that this incentive would have little chance of having a significant impact. Although the individuals contacted had no quarrel with the concept that basic research activities are necessary for efficient development of new pesticide compounds, they did disagree that efforts to fund such programs could have much impact in meeting the goals of the EPA/ETIP program.

There are two reasons for this disagreement. If it is envisioned that such basic research programs have an application, they (according to industrial and governmental interviewees) become a political football; that is, pressures are brought to bear by various agricultural and industrial groups to have such programs support efforts leading to the direct benefit of the lobbying group. However, if such basic research programs are truly non-directed, the impact of the $10-25 million in additional funding would be lost against the background of the existing basic research establishment and the existing body of undigested basic research data.

The view has been expressed that at least one benefit would be an increase in skilled researchers for industry (since part of this funding would support the training of additional graduate students). However, this effect cannot now be considered a positive aspect of this incentive, because the NSF and Department of Labor already predict a surplus of biologists over the next decade.

(3) Long-Term Consequences

Major long-term effects of this incentive cannot be predicted.

E. REQUIREMENTS FOR SUCCESS

(1) Barriers

No technical barrier is envisioned to the successful incentive implementation. A real barrier is envisioned at the political level. Given the current mood of Congress, the poor justification for implementing this program, and the absence of effective lobbying groups who would strongly support it, it seems unlikely that Congress will authorize $100 million ($10-25 million for at least five years) to implement this incentive.

The other barrier which exists is political/administrative in nature. It must first be resolved whether NSF, USDA, EPA or another agency will control this program. Associated with this question is the concern that the new $10-25 million program will subtly divert resources from those agencies not involved.

(2) Overcoming These Barriers

These barriers can be overcome only by accumulating information which provides firmer justification for this incentive. Some of this new data probably will also provide a firmer basis for placing this program under a particular agency.

F. SUMMARY OUTLOOK

This incentive will probably not be implemented because of congressional reluctance to allocate the necessary funding. If implemented, this incentive could be expected to have only a minor impact in stimulating the development of commercial innovative pesticides.

- Meetings and training courses: Although the most effective training is conducted by county extension agents working individually with farmers right in their fields, classes at extension centers are less expensive and still allow personal contact between instructors and growers.

- Manufacturers' literature, dealers, salesmen, and labels: In studies of various sources of information cited by growers; these rank consistently high. Sales literature is typically attractive and plentiful. Salesmen are motivated by a single, clear goal--to carry their messages about their own products right to growers. By contrast, state and county extension agents typically have a broader range of material to bring to the attention of farmers, and must be knowledgeable about farm practices other than pest control. In some areas, commercial dealers and salesmen outnumber extension agents by far.

- Independent pest management consultants: These relatively new actors, playing roles similar to those of doctors and veterinarians, can offer objective and up-to-date counsel. But they are still few in number, they must charge fees (if not salaried employees of corporations), and hence they benefit mainly well-to-do and sophisticated growers and agri-business firms.

- Extension specialists and agents: Guided by a long and honored tradition, they can be both accepted and effective. But demands on their time and knowledge are many. They can also feel torn between their traditional goal of increasing productivity and the new goal of checking environmental damages.

Of these several information-giving methods, the most effective one available to government is the cooperative federal-state-county extension service. The century-long record of extension work includes notable achievements in transferring modern agricultural improvements from laboratories to fields. Therefore, the network of county agents would seem to offer the ideal way to train growers in the technology of improved pest control methods.

The relationship between the USDA Extension Service/Cooperative State Extension Services and the independent pest management consulting industry is complex. Because the USDA pilot projects are relatively new (the last 4 years), the relationship between the public and private sector in this context has not yet been fully worked out; but it should and can be complementary. Presently, many farmers are dubious about the economic benefits of retaining independent consultants. Thus it is difficult for private firms to establish themselves in business. And thus the extension service performs a valuable service by subsidizing a project (on a limited basis) which can serve to establish the effectiveness, reliability, and economics of field scouting and judicious application of pesticides or the use of other techniques if and when needed. After the value of these techniques have been rather firmly established in a locality, experience

INCENTIVE 5. INCREASE INFORMATION AND TRAINING FOR USERS[*]

A. PROBLEMS ADDRESSED

Several types of changes in recent years--in scientific knowledge of various pests, in pest control methods, and in governmental regulation of pesticide use--have increased the difficulties facing farmers and commercial applicators. In addition to learning about which pesticide combats which pest, they must learn more about figuring dosage for each crop or condition, using nozzles and other application equipment properly, conforming with label instructions, identifying pests and choosing control methods accurately, and disposing of containers safely. They must also follow government regulations which require users of restricted use pesticides, whether private or commercial applicators, to be trained and certified. The training and certification programs required by FIFRA, as amended, will involve an estimated 2,000,000 private and 200,000 commercial applicators; initial certification must be completed by October 21, 1977.[**] Often, the nature of new pesticides requires that they be applied with more precise timing, which in turn demands more scientific and managerial effort by farmers. In summary, because the use of pesticides is becoming increasingly complex, the need for complete, accurate, and timely information and training is increasing. Moreover, USDA needs effective ways to inform growers and applicators of new, alternative, and environmentally more acceptable pest control methods, and EPA needs ways to inform them about both regulations and voluntary compliance programs.

A variety of methods exist by which farmers normally learn about new agricultural knowledge and practices developed in university labs. Each method has distinct advantages and weaknesses:

- Experience, neighbors, and peers: Although time-honored and least expensive, such learning is inherently slow and uneven; it also lags rapid changes in agricultural science and technology.

- General farm magazines, books, bulletins, radio-TV, and demonstrations: These broadcast methods, while relatively inexpensive, rely upon users to translate the information to their own conditions.

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[*] Based upon preliminary incentive 36 (Training of Farmers and Applicators) and 58 (Expansion of Extension Service Program).

[**] Bergman, Paul W., (entomologist, Extension Service, USDA), The Development and Validation of a Standardized Achievement Test for Certification of Commercial Pesticide Applicators, Ph.D. Thesis, University of Maryland, 1975, p. 4.

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- Meetings and training courses: Although the most effective training is conducted by county extension agents working individually with farmers right in their fields, classes at extension centers are less expensive and still allow personal contact between instructors and growers.

- Manufacturers' literature, dealers, salesmen, and labels: In studies of various sources of information cited by growers; these rank consistently high. Sales literature is typically attractive and plentiful. Salesmen are motivated by a single, clear goal--to carry their messages about their own products right to growers. By contrast, state and county extension agents typically have a broader range of material to bring to the attention of farmers, and must be knowledgeable about farm practices other than pest control. In some areas, commercial dealers and salesmen outnumber extension agents by far.

- Independent pest management consultants: These relatively new actors, playing roles similar to those of doctors and veterinarians, can offer objective and up-to-date counsel. But they are still few in number, they must charge fees (if not salaried employees of corporations), and hence they benefit mainly well-to-do and sophisticated growers and agri-business firms.

- Extension specialists and agents: Guided by a long and honored tradition, they can be both accepted and effective. But demands on their time and knowledge are many. They can also feel torn between their traditional goal of increasing productivity and the new goal of checking environmental damages.

Of these several information-giving methods, the most effective one available to government is the cooperative federal-state-county extension service. The century-long record of extension work includes notable achievements in transferring modern agricultural improvements from laboratories to fields. Therefore, the network of county agents would seem to offer the ideal way to train growers in the technology of improved pest control methods.

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Despite the need and demand for services in entomology, plant pathology, and weed sciences, however, the extension system appears to be handicapped in responding. Recent studies (the latest being that conducted in 1974 for EPA for von Rumker and Horay*) have reported that government extension agents and similar non-commercial sources are generally outranked by pesticide sales literature and dealers, each promoting his own company's products, as sources of information and advice used by growers. A study from Lousiana State University reports that the amount of working time which Louisiana county agents devote to entomological problems has declined markedly over the past two decades, from up to 30% in 1956 to about 15% in 1974. Although about one-third of all queries received by Louisiana county agents concern pest control problems, only about 4% of the typical agent's college training has been in entomology. Knowledge both about pests and about methods of controlling them has grown considerably more sophisticated over the two decades, but the amount of college training given to county agents in Louisiana has not changed appreciably.** Other observers suggest that not enough of the good research being conducted in laboratories and experiment stations is transmitted via the cooperative extension services to growers and pesticide users. Finally, transmitting new research results in entomology and other disciplines relevant to pest control requires skills beyond those traditionally associated with agricultural county agents:

> "...pest management programs are developing and the need for a new class of trained personnel is evolving. These personnel must be trained in principles, such as biology, population dynamics, economic thresholds, and sampling techniques for pests. They must be capable of conducting an integrated program of applied methods consisting of biological, cultural,

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*von Rumker, R. and F. Horay, Farmers' Pesticide Use Decisions and Attitudes on Alternate Crop Protection Methods, EPA Report 540/1-74-002, 1974.

**Alford, Arthur R., An Evaluation of the Role of Entomology in Louisian Agriculture, Master's Thesis, Louisiana State University, Baton Rouge, 1976. Similar studies showing similar findings from other states are reported by Bergman, Paul W., The Development and Validation of a Standardized Achievement Test for Certification of Commercial Pesticide Applicators, Ph.D. Thesis, University of Maryland, 1975, pp. 44-45.

physical, mechanical, chemical, and regulatory practices, in addition to using natural control factors in manipulationg pest populations in a systems approach. Extension must adapt this type of training to continuing education programs, refresher courses, or post-academic education or training."*

This incentive outlines a program, both familiar and practical, by which EPA and USDA can increase the information and training available to pesticide users.

B. BACKGROUND

Recommendations about improved agricultural practices and technology in general are transmitted from research laboratories to farmers via the extension services. Pest control recommendations in particular flow along a chain consisting mainly of the:

- research specialists in entomology, plant pathology, weed science, and nematology, working on basic scientific problems in laboratories at the state land-grant university;
- extension specialists, based at the state experiment field station(s) to provide specialized technical assistance to county agents and the public of the state (or several counties);
- county agents, the primary deliverer of the full range of extension services to all farmers in one county; and
- farmers or commercial applicators who buy and use pesticides.

Others contribute to the information dissemination process, for example, administrative managers of federal and state extension programs and independent pest management consultants. But the basic and most important links in the chain are the four listed above.

However, the number of pest control specialists is not large in relation to the demand for their services and the growing complexity of the knowledge base. Moreover, the certification requirements of FIFRA, as amended, changed significantly one aspect of traditional extension work; whereas other programs are offered to farmers for them to accept or decline voluntarily, the law makes their participation in the certification program mandatory if they apply restricted-use pesticides.

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*Bergman, Paul W., (entomologist, Extension Service, USDA), "Review of Current Extension Training Programs in Pest Control Technology," paper presented at the Entomological Society of America meeting, December 1, 1971, p. 3.

Recognizing the special needs created by FIFRA, as amended, Congress appropriated $5 million over two years for a special program to encourage and assist states to train applicators in pesticide use. This financial aid was channeled from EPA through USDA to cooperating states, for the purpose of stimulating states first to develop training programs and then to continue them after federal funds expire. Not all states have responded enthusiastically or uniformly and not all potential applicators have been trained. Moreover, the federal contribution is scheduled to expire this year, and doubt exists whether states will supply funds to continue this newly launched training.

One form of training assistance is a series of 13 manuals with related audio-visual aids, designed jointly by EPA's Pesticide Operations Division and USDA's Extension Service. Two are core training manuals, one for commercial and the other for private applicators, which were completed and published only in 1976.* The remainder, now in various stages of preparation, correspond to the categories of commercial applicators designated in the FIFRA regulations, and are being designed to bring applicators up to standards of competency, as specified by regulation:**

1. agricultural pest control--plant and animal,
2. forest pest control,
3. ornamental and turf pest control,
4. seed treatment,
5. aquatic pest control,
6. right-of-way pest control,
7. industrial, institutional, structural and health-oriented pest control,
8. public health pest control,
9. regulatory pest control, and
10. demonstration and research pest control.

Extra manuals will cover aerial application and food processing.

Their general purpose is to offer technical information to state extension services, which in turn may adapt them to their own needs and training methods. Written on contract by groups of university and extension experts, these manuals are intended to be authoritative statements of principles of specific standards on environmental safety, user safety, and labeling, which should guide all pesticide users. EPA, together with USDA, may develop other manuals addressed to the special needs of pesticide salesmen.

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*U.S. Environmental Protection Agency and Department of Agriculture, Apply Pesticides Properly--A Guide for Commercial Applicators, Washington, D.C., 1975, 35 pp; and EPA, Apply Pesticides Properly--A Guide for Private Applicators, Washington, D.C., 1975, 24 pp.

**Federal Register, Vol. 39, No. 197, III, pp. 36450-2.

Only a handful of training specialists work full-time out of EPA headquarters, and occasional help for states comes from pesticide personnel in EPA's regional offices. However, these specialists are limited not only by their small number, in relation to the number of states and users, but also be federal policy which prohibits EPA from providing direct training without charge. Thus EPA can only offer training support and technical assistance, and mainly through the broadcast method of publications. However, EPA trainers can be detached for temporary duty with USDA or a state extension service. Furthermore, EPA's facilities at Cincinnati offer potential for becoming a national training center and a base for producing instructional materials and supporting a larger training staff.

Against this background, several issues stand out. The cooperative extension system, with its tradition of accomplishment in modernizing American agriculture, offers a ready network for training. The value of the extension system's work is freely acknowledged by industry, which strongly endorsed this incentive when first proposed. County agents are now being trained for certification as commercial applicators, and will in turn become trainers of farmers and commercial applicators. However, this duty adds a heavy burden to men already overloaded with other responsibilities. The corps of extension specialists is the best and most logical resource to supplement the efforts of county agents. But the number of these specialists seem too small in relation to the task at hand; moreover, the stability of long-term financial support at the federal level seems uncertain. It should also be noted that the need of training is not a one-time-only phenomenon. The most immediate need today is to train applicators for certification by the October, 1977 deadline set by FIFRA, as amended. But then a secondary or follow-up stage will be needed to provide refresher training, for certified applicators, to keep them abreast of new developments, and elementary training for new applicators entering the field.

C. SPECIFIC INCENTIVES*

This incentive proposes roles at the federal level both for EPA and for USDA, because each has distinctive contributions to make. EPA has the legislative mandate, organizational motivation, and special knowledge needed to promote voluntary compliance related to environmentally acceptable pest control methods; however, its role as educator and promoter is likely to be curbed in the long run by its role as the enforcer of pesticide regulations. USDA has the authority, tradition, and skills to use the cooperative state extension services as vehicles for informing and training users.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentive for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

This incentive's long-range goal is to stimulate market demand for improved pesticides. To achieve the goal requires increasing the interest and willingness of growers to use pesticides with more precision. It also requires transmitting more current information to educate pesticide users about the increasing number of alternative pest control methods and materials.

The incentive proposes increased federal funding to expand information and training services in three specific ways:

- more extension agents specializing in entomology, plant pathology, weed science, and nematology;
- more training materials to disseminate up-to-date knowledge; and
- more training courses to serve various groups within the pest control community.

One characteristic of this incentive is that it is incremental. It does not propose new concepts or programs. Instead, it reflects that consensus of our industry and government respondents that improving present information and training programs will help increase both proper use of pest control methods and grower demands for improved pesticides. It would merely continue government's traditional role of promoting better agricultural practices and greater output while also protecting the health and safety of citizens. In this case, three kinds of safety are included--immediate safety of the pesticide user while applying toxic chemicals, longer-term safety of the user from build-up of toxic materials in his working environment, and safety of consumers who ingest food treated with pesticides. Thus, this incentive proposes only incremental changes using existing legislative authorities, established organizational relationships, and proven pedagogical methods.

Another characteristic is that this incentive works indirectly. It does not offer dollars or skills or other resources to pesticide manufacturers directly. Instead, it channels them from EPA and USDA to state departments of agriculture, state land-grant universities, extension specialists, county agents, and other extension workers to the applicators and growers who buy pesticides from agrichemical firms. Although this sequence is long, and may seem somewhat cumbersome, its usefulness is dictated by tradition, economy, and effectiveness. Moreover, it fits the familiar pattern of government providing the general infrastructure services needed by the economy, including ports, highways, education, and (the most successful example of them all) the agricultural extension system.

The main actors in this incentive are those in the sequence. However, active or tacit approval would also be needed from Congress, the Office of Management and Budget, state legislatures (because extension services are two-thirds funded and controlled by the states and counties), extension service administrators, and the various interest groups clustered around each step in the sequence.

The two most important links in the chain for transmitting new agricultural technology are the extension specialist and the county agent. They provide the primary links between the industrial and/or scientific community and the farmer. The county agent's function is to serve growers as the initial source of general information about the value and use of new methods or technology. The extension specialist provides more detailed and specialized technical assistance on pest control to the county agent and directly to the farmer. Thereafter, the commercial firms, farmer-to-farmer or peer group communications, and extension service education programs, are expected to provide day-to-day information to applicators and growers.

Implementation of this incentive would be carried out in the following basic steps:

- Needs assessment. Training specialists from USDA, EPA, and cooperating states would jointly review present federal and state pest control information and training programs to accurately assess needs and objectives, both for initial certification as required by October, 1977 and for continuing education thereafter. Primary data inputs for this review should come from state and county extension sources, to reflect local training experience and local knowledge of grower needs. The result of this needs assessment would include forecasts of required number of various types of extension personnel such as application specialists, the costs and time required to bring them into active service, and the priorities for serving geographic areas and functional needs--for example, entomology, plant pathology, weed science, and pesticide safety. This review should also assess the knowledge and demands of the many audiences (Bergman's 1971 study identified 34) to be trained and the resulting variety of training materials and formats required (for example, meetings, demonstrations, correspondence courses, media broadcasts, and short courses).

- Program planning. This needs assessment would provide the data for developing program plans, which should build upon the present EPA, USDA, and state training programs. These plans should propose training materials and courses of sufficient variety and convenience to attract the several target audiences. The plan should recognize and exploit the natural potential for synergy between this general pest control training program and the integrated pest management efforts.

- **Estimate and obtain funding**. The program plan would become the instrument for obtaining the necessary top-level support within EPA, USDA, OMB, Congress, and the participating state extension services. Although the initial planning might be funded from discretionary budgets within EPA and USDA, the full program over several years would probably require congressional renewal of the appropriations due to expire soon.

- **State extension services**. Each state would develop its own plan (or refine its existing plan) to provide training tailored to the needs of its own farmers and to staff the program properly. The state plan would meet the requirements of the designated state lead agency, typically the state department of agriculture, for pesticide certification training. State and county extension personnel, using the full range of both traditional and newly developed techniques and materials, would provide continuous services to private and commercial applicators about new and improved pest control methods. Extension services should be backed by the skills and facilities not only of the land-grant universities but also of manufacturers and trade associations to update information about their products and techniques. Moreover, they should enlist the cooperation of vocational education schools in bringing pest control training into agriculture classes.

- **USDA's role**. USDA's Extension Service would provide its normal federal leadership function of supporting state extension services with funds and technical guidance, as well as provide liaison required for EPA and the states to work effectively together. In particular, USDA would be the national clearinghouse for information and perspective about extension training efforts for pest control. It would, for example, provide data from which land-grant universities could estimate future market demands for various types of specialists, and adjust their enrollments and curricula accordingly.

- **EPA's role**. EPA would strengthen its training program by:

1. Increasing, as needed, EPA funds channeled to cooperating states via USDA;
2. Stepping up production of those specialized training materials which EPA is best qualified to create;
3. Providing technical specialists to assist USDA and participating states in conducting training;
4. Providing direct training not available from other federal or state agencies; and
5. Training EPA's headquarters and regional personnel to improve their knowledge of and efficiency in administering pesticide regulation programs.

EPA's training efforts would focus on voluntary compliance and those needs which cannot be satisfied better by other federal agencies, for example, pesticide users in cities, industrial areas, and in such public institutions as hospitals.

- Monitoring and evaluation. Finally, EPA, USDA, and the several states would periodically review the program's progress to assess strengths and weaknesses and to take corrective actions.

This program would appear to satisfy several criteria for a good incentive, namely significance, feasibility, acceptability, benefits for a variety of parties-at-interest, visibility, and potential for becoming self-sustaining.

D. POSSIBLE RESULTS AND IMPACTS

Estimating costs for this training program is difficult, because operating data from its initial years are only now being assembled by the states. Indeed, a major result of the first two steps--needs assessment and program planning--would be a detailed and accurate cost estimate. However, it seems likely that another $3-4 million would be needed both to complete the initial certification training program and to launch the recertification and continuing education program on a stable basis. Thereafter, perhaps $1-2 million would be required annually to maintain the coverage and standards envisaged by FIFRA, as amended.

Evidence of success from this incentive would be difficult to trace clearly, because of the long chain of required interactions and the many external factors influencing the actors, in addition to the usual difficulties of measuring educational outcomes and behavioral changes. But some results of improved funding and organizational delivery capacities would probably be seen within three to five years, in the form of rising market demand for some pesticides. Evidence of widespread adoption of improved pest control techniques could probably be only implied. However, the historical record of the cooperative extension system in speeding the introduction of new technology would provide baseline data for at least estimating the degree of success.*

Various parties affected by this incentive would find in it various benefits. For EPA, it would offer a vehicle for:

- Strengthening its present pesticide program,
- Improving or developing cooperative relationships with USDA and state extension services,
- Learning more about user needs, and
- Disseminating a greater volume of accurate information about environmentally safe pest control methods.

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*Bergman, op. cit., developed the methodology for measuring achievement by student commercial applicators.

For USDA and affiliated state extension services, it should offer a means for:

- Gaining support of environmental groups for needed pesticide programs,
- Increasing the expertise and sophistication of their staff, and
- Gaining favor with growers by providing the practical assistance which they are demanding.

For private and commercial applicators, it should offer:

- Prompt and inexpensive introduction to new pest control methods, and
- Knowledge of methods and pesticides which are both effective and safe by EPA's standards.

For agrichemical companies, it would offer:

- A form of indirect subsidy for marketing, especially of improved pest control methods, and
- Possible erosion of demand for some established and environmentally less acceptable pesticides.

E. REQUIREMENTS FOR SUCCESS

Although the program outlined above is already familiar and exists in basic form, its full implementation and expansion would not be accomplished without some difficulties. These would be not so much technical, as political and administrative. However acceptable this incentive might be as a concept, its likely price tag (to be determined in detail by the needs assessment) would throw it into competition with other programs for the limited funds of EPA and USDA. Thus, the program plan must be well developed and persuasive not only for pesticide training specialists, but also in the eyes of the top-level generalist administration and budget managers at USDA, EPA, and OMB. Only after their approval could it be presented to congressional committees for legislative authorization and funding. Moreover, since state extension service can opt in or out as they choose, and since states would be expected to assume greater responsibility for the program over a period of years, any program plan would also have to be sold to as many of them as possible.

To overcome these barriers, the first step would be to accurately assess needs and articulate a program plan with costs, deadlines, and expected results. The program should emphasize training of high quality, a variety of offerings to suit the special needs of various audiences, and formats and schedules to suit the convenience of those audiences. The next step would be to develop a persuasive inventory of benefits which the program would bring, especially to farmers, commercial applicators, pesticide manufacturers, and national agricultural productivity. This inventory would help to enlist the support of farm and industry associations for gaining approval and funding by Congress. Although such support has been lacking in the past, the ample evidence of user demand for more training seems likely to reverse that early opposition.

F. SUMMARY OUTLOOK

This incentive has both merits and weaknesses. Its advantages include being familiar in concept, enjoying broad support, building on precedent and existing organizational patterns, and offering benefits to various parties of importance to EPA and USDA. However, it would cost money, attract less excitement and attention than a dramatically new concept, rely upon action and cooperation by a long chain of participants, and produce results that would be discernible only beyond the immediate future, and thus be difficult to evaluate accurately.

On balance, this incentive embodies compromises: although not exciting, it offers reliability; although familiar, its familiarity can be its political strength; although requiring funds, expenditures can be controlled and expanded slowly with experience; even if costly, investments in extension education have historically contributed greatly to the success story of modern American agriculture; and, although relying on cooperation between EPA and the agricultural community, with their recent history of antagonistic relations, it offers a means for building harmony on the basis of mutual needs, including agriculture's needs for safer and more effective pest control methods.

INCENTIVE 6. LENGTHEN PATENT LIFE*

A. PROBLEMS ADDRESSED

Pesticide manufacturing companies rely, more than most business firms, upon patent protection. Their proprietary technology can be developed only at great cost. If marketable formulations could merely be copied by competitors for profitable products, their inventors and developers would have no way of recouping their sizable investments. Thus, a key element in the business strategy of a pesticide manufacturer is legal protection of its proprietary technology for a period which is known and guaranteed.

A patent, in effect, certifies a bargain. On one side, an innovator reveals the secret of his technology to the public. In return society acting through the government's patent office, gives him permission to exclude others from practicing his invention for 17 years. During this period, other innovators are challenged to improve upon the published state of the art by inventing their own distinctly different and improved technology. Thus, the patent device provides inventors with an incentive to create new solutions to problems, and the patent system gives society a continuous flow of new technology.

Recently, however, the fixed 17-year period of patents held by pesticide manufacturers has, in effect, been shortened. This effection reduction of protection has resulted not from changes in patent policy and law, but from the growing length of time needed by EPA to register each new compound or use for marketing. Thus, the government is excluding the manufacturers from practicing their inventions during the period of registration delays.

Both the process and the time required to obtain registration present pesticide manufacturers with difficult problems. Because EPA's registration applications are open for inspection by the public and therefore by competitors, a manufacturer must apply for a patent before applying for a registration permit. Although the notice of "patent pending" does not guarantee protection, it does show that an application has already been filed; this favors the first applicant because patent courts require a greater burden of proof from later applicants; moreover, "patent pending" warns potential competitors that if a patent is granted, costly law suits may follow if they challenge the patent.

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*Based upon preliminary incentive 49 (Modification of Patent Issue Date and/or Duration).

Another problem for a manufacturer is timing. If he files patent and registration applications early in the developmental stage of a pesticide material, he runs the risk that problems will lengthen the time in registration, and thus shorten the time available within the 17-year patent life for marketing the product after approval. But if he delays, he runs the risk that a competitor will apply for patent protection for the same product and thus gain the advantage of the first position.

To protect his proprietary technology, therefore, the pesticide manufacturer usually feels obliged to apply for a patent early in a product's development, especially because of the review time needed by the Patent Office before it decides. Frequently, the patent must be obtained two to four years before the product or process can be sufficiently developed and tested to permit registration and sale. Thus, the period of patent protection is effectively reduced from its potential 17 years to 13-15 (or less) years. This erosion in time available to recoup and profit from original investment is generally assumed to be a deterrent to potential and some present manufacturers.

B. BACKGROUND

One pesticide manufacturer's unsuccessful attempts to initiate changes illustrate the several difficulties in the incentive concept. In the late 1960's, one of the company's products was affected by erosion of its patent life. The company's legal counsel drafted a bill which, if enacted by Congress, would have allowed the patent life of any proprietary product to be lengthened by the amount of time lost from the normal 17-year period because of regulatory procedures. The bill was drafted broadly, on purpose, to include all proprietary products, so as to establish the principle of compensation, to forestall the rebuttal or exceptionalism, and to attract support beyond the pesticide industry. It did attract support from members of the National Agricultural Chemical Association. But it was opposed during discussion in the forum of the American Patent Law Association by the drug industry, which was then preoccupied with fighting more serious political threats in the Congress. Therefore, that draft bill died. Moreover, although other pesticide companies supported the proposal in general, none seemed to be willing to spend resources or to push it actively, perhaps because none was being hurt specifically.

Two years later, the company's counsel drafted a narrower proposal, this time singling out pesticide manufacturers for remedial compensation. The company's statement recalled that:

> "In 1968, we pointed out that owners of patents covering products whose only substantial commercial use is in a field of commerce subject to regulation by the Federal Insecticide, Fungicide and Rodenticide Act are effectively deprived of the full benefit of their patent whenever compliance with said Act (as well as the related provisions

> of the Federal Food, Drug and Cosmetic Act) and the regulations issued thereunder compel postponement of commercialization beyond the issue date of the patent. This inequity operates to reduce the patent incentive in precisely those areas of commerce where the public interest demands that the incentive be fully maintained.
>
> "We therefore suggested that the patent laws should include a provision to the effect that when the only substantial commercial uses of a patented product are uses subject to regulation by FIFRA, and when commercialization of the product is prohibited until regulatory requirements are met, the term of the patent should be extended by a period of time equal to the time lost in complying with such requirements."

But difficulties existed in the idea. For example, what level of commercial use would be "substantial," and in what forum would such questions be resolved? Therefore, the second version proposed:

> "To avoid these difficult subjective questions and at the same time remedy the underlying inequity without improper enlargement of patent rights, an alternative approach seems feasible and has been reflected in the attached draft bill. This approach is based on the premise that if a patent owner believes that his patent is of little or no value to him in fields outside that subject to regulation by FIFRA, he may be willing to surrender his patent rights in such fields in exchange for an extension of the patent term in the regulated field to compensate for time lost in the regulatory process. This would not only remedy the inequity and maintain the full patent incentive, but would have the added social advantage of opening the patent to free exploitation by third parties in other fields far earlier than would otherwise be possible."

This second draft thus sought a remedy which would allow third parties to exploit the technology in fields beyond the concern of FIFRA far earlier than normal. But when this version drew a strongly negative response from the relevant committee of the American Patent Law Association, the company dropped its initiative.

C. SPECIFIC INCENTIVES*

Two ways to preserve patent life by compensating for time lost in the registration process have been suggested. One would be simply to lengthen the period of protection available for pesticide manufacturers by a fixed amount, perhaps by three years to total 20 years. The other would be to lengthen the period by a variable amount, equal to the time lost in complying with registration requirements for each compound or use; in effect, protection would begin on the date when the Patent Office issues its patent, but the 17-year meter on exploitation would begin to run only on the date when EPA issues its registration permit. Both ways would require new legislative authority.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

A bill proposing general reform of the patent system was easily passed by the Senate in 1971 (as S.2255) but no action was taken by the House Judiciary Committee or the full House, and hence the bill died when the 94th Congress ended. The same or a similar bill may be introduced when the 95th Congress convenes in 1977; however, changes in committee memberships would probably change the nature of debate and likelihood of passage. S.2255 proposed to change the term of patent protection from 17 years from the issuance of the patent to 20 years from the date of filing. While it is possible that this would extend patent protection, it would be more likely to diminish it.

The proposed new system would require inventors to apply for patent protection immediately upon making their discoveries or developing their new technologies. This change would not only remove an element of discretion from the strategies open to pesticide companies, but also leave the life of their patents exposed to erosion by the time absorbed by EPA's registration process.

This change would further reduce the present options available to companies. They are allowed to initiate an unlimited number of continuations, for example, to add newly developed information in support of the initial application for a patent. Today's right of unlimited continuations gives applicants a tool for delaying the starting date of patents, and thus for offsetting delays which occur in obtaining EPA's registration. The current effort of the Patent Office to reduce pendency time has of necessity increased the number of continuation applications being filed. The proposed system would limit the number of continuations which applicants could request.

The bill proposed that applications be published within 18 months of filing, which is current practice in Belgium, Germany, Holland, and Japan. This proposal would make a company's new technology or formulation known to the public earlier than is now the pattern. Potential competitors would therefore be given information earlier upon which they might either file a protest or commence research and development of a different but better product to present a challenge in the marketplace.

Other provisions of the proposed system would increase documentation requirements and legal work markedly. Some observers predict that the resulting new fees alone would fall with special harshness on small firms. Because small firms often depend upon patent protection for their early existence and growth, they could be effectively priced out of such protection, and hence barred or driven out of the pesticide market. Thus, the reform bill, if enacted, would be likely not only to reduce the options presently available for delay, but also to add more barriers to those already faced by small companies.

Although the bill may not pass the House during this Congress, and thus have to be refiled in the new Congress in 1977, its existence remains a danger to various industries for various reasons. In these circumstances, it seems unlikely that the pesticide industry can elicit much support for the bill from other industries more worred about their own patent problems.

D. POSSIBLE RESULTS AND IMPACTS

The expected results of so lengthening the life of a pesticide patent in order to preserve its useful market life would be that companies would be willing to invest the costs of registering their new products more readily than under present circumstances. This effect would begin to become apparent within two to four years after the practical patent life was initially extended. The results of the encouragement to develop new products would take longer and probably would not be apparent for six to ten years. The duration of the effects, assuming to further changes in the patent law, would extend indefinitely into the future.

E. REQUIREMENTS FOR SUCCESS

Obtaining the required legislation would be a lengthy process, even under the best of conditions. Only Congress may grant an exception to lengthen the life of a patent. This has reportedly happened only once, concerning the then-unusual technology of atomic energy and during the national emergency of World War II.

The normal time required for a major new proposal to be examined and accepted by Congress is about five years. If EPA were to propose or endorse such a bill, it would have to obtain clearance from the Office of Management and Budget, where it might be questioned by Justice's Anti-Trust Division. The legislative process includes hearings and votes by subcommittees, full committees, Senate and House, and conference committee, as well as approval by the President. No single company or government agency acting alone would be likely to obtain such a change in patent law.

To run such a proposal successfully over many hurdles would thus require not only energy, skill, persistence, and luck, but also support by a broad coalition of interests. These difficulties help to explain why the concept of lengthening patent life, even though attractive as an idea, requires sustained endorsement from pesticide manufacturers to translate it into action. The concept did receive general support from representatives of manufacturers who attended the October 1976 workshop at the end of this study.

Other practical considerations are also deterrents. The lure of longer patent life is the theoretical prospect of reaping larger profits 15 years or more in the future. But a new pesticide product carries no guarantee of continuing to sell as strongly at the end of its patent life as at the beginning. Changing consumer needs, unexpected side effects, competition from newer products, and other problems can be expected to reduce a new product's potential span of maximum earning power to only about ten years. Therefore, manufacturers naturally plan to recover their investment, if possible, within the first few years after a product enters the market.

A related financial consideration is that expected inflation makes the present value of profits anticipated 15 years ahead relatively small. This inflationary factors as well as other uncertainties inherent in projections so far into the future is likely to reduce the effects of lengthened patent life on current decisions about increasing expenditures on R&D. Thus, even though the idea of extending patent life readily gains approval from everyone, its results are likely to be only marginal.

F. SUMMARY OUTLOOK

Lengthening the life of patents in order to preserve the 17 years of useful market life is an idea attractive to all, perhaps especially to small companies. But it faces obstacles of some magnitude. In essence, Congress may be reluctant to legislate an apparent exception to a major principle of public policy for one industry which would surely lead to requests for exceptions from many. Pesticide manufacturers could, of course, try to mobilize a broad coalition of industries to support general modifications. But such a campaign would be costly. Even though pesticide manufacturers would welcome changes, the present patent situation may not seem threatening enough to stimulate their concerted action in support of major changes. However, the Executive Committee of the National Agricultural Chemicals Association recently reaffirmed its endorsement of the concept as an important incentive which the industry should support.

Changes in the Congress, the process for issuing patents, and EPA's process for registering new products may eventually combine to make the concept of compensating for erosion of patent protection politically viable. The Patent Office has recently reduced the normal period between application and award to about two years. If the registration period is not also reduced, effective patent life will be shortened still more. To the extent that this becomes a serious disincentive for companies to invest in R&D, EPA should see merit in joining the industry in endorsing the concept as part of a general revision of the patent system.

INCENTIVE 7. IMPROVE COMMUNICATION BETWEEN PESTICIDE INDUSTRY AND THE EPA*

A. PROBLEMS ADDRESSED

There is a need for better communication between industry and the EPA. Without question industry must be more sensitive to EPA's needs and problems, and vice versa. Concern was expressed by several industrial sources, one complaining that communication was "pretty one-sided." This incentive could be implemented quickly and show beneficial results without significant expenditure of funds or the need for administrative or legislative action outside of EPA.

This incentive is closely related to the problem of removing the uncertainties in the registration process and improving its efficiency and speed.

Its long-term effect would be to improve the speed and effectiveness of registration and would help remove many of the uncertainties and misunderstandings that currently exist between the EPA and the pesticide industry.

B. BACKGROUND

Communications between the EPA/OPP and the pesticide industry occur primarily in the process of registration or reregistration of pesticide products; in the providing of data and information required by current regulations; in written documents such as proposed guidelines, regulations, policy statements and strategy documents which are sometimes circulated to industry in draft form prior to publication in the Federal Register in response to these documents; and in public hearings and adversary proceedings. Professional meetings in which EPA and industry both participate are relatively few; informal communications and meetings are few, but increasing. Industry meets more frequently with representatives of the USDA, universities, state extension services, and other groups who are in close communication with pesticide users.

EPA has recently announced an open information policy and has made conscientious efforts to provide industry more information on its current thinking and planning. In spite of EPA's role as a regulator, there needs to be more frequent and open channels of communication on an informal basis to help both parties gain a better understanding of each others' and common problems, needs and potential solutions.

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*Based on suggestions by representatives of the pesticide industry during review of the "Interim Working Document."

C. SPECIFIC INCENTIVES

One means of improving communications between the EPA and the industry would be to establish informal joint committees that would meet periodically to discuss common problems. This is the recommended approach.

There probably should be several committees, each made up of members from industry and the EPA. These members should have equal levels of authority or common policy or technical interests. A variation of this approach has been used very successfully to improve communication between the Food and Drug Administration and industry.

Rather than acting as another committee to duplicate the efforts of the Pesticide Policy Advisory Committee, the proposed committee (or committees) would have the objective of finding ways to understand the problems EPA faces in dealing with pesticides and those faced by the pesticide industry.

Members of the committee(s) should come only from these two groups. With a better understanding of mutual problems, the committee(s) would seek means of resolving the problems to the satisfaction of both interested groups. One would expect that in many instances the work would go beyond merely the interchange of ideas, and possibly require ad hoc subcommittees to research particular problems and recommend courses of action to the committee. Even if some problems cannot be resolved, at least the problem would be understood better, and better understanding should lessen the adversary roles frequently encountered in EPA-industry dealings. In many instances, however, these periodic meetings should result in specific recommendations for action by the FDA, industry or both.

Representatives of industry or the committees could be selected through an industry association such as the Manufacturing Chemists Association (MCA) or the National Agricultural Chemical Association (NACA). Another approach might be to use currently established committees as the nucleus of industry representation. For example, the Research Directors Committee of the NACA or the Environmental Council of the American National Standards Institute may be representative groups for industry at the policy-making level, while the American Society for Testing and Materials (ASTM) Committee E-35 on Pesticides may be a promising pool from which committee members could be selected at the middle and technical levels. EPA's representatives on the committee should have sufficient authority within their activity to be able to make changes in EPA procedures as recommended by the committee(s). Similarly, industry representatives should be of such stature that their recommendations to industry would be respectfully considered by other companies.

The proposed committee would enhance its value if it circulated the mutually agreed upon synopses of each meeting widely within the EPA and pesticide industry.

Initially, the senior level committee should be set up, to be followed if the need became clear, by one or two committees which would focus on specific problems and their resolution.

D. POSSIBLE RESULTS AND IMPACTS

We expect the implementation of this incentive would lead, at the very least, to a better mutual understanding of each group's problems, and could lead to much improved efficiency in the registration procedure and regulatory relationship with industry.

E. REQUIREMENTS FOR SUCCESS AND EFFECTIVENESS

The requirements for success are primarily an open mind on the part of both parties, the selection of appropriate representatives for each group (e.g., large and small companies, those with chemical and biological interests, the wide dissemination of the results of their discussions, and willingness of all to implement mutually agreed upon recommendations.

F. SUMMARY OUTLOOK

The chances of success should be good. There is a recognized need (certainly on the part of industry) for better informal exchange of views. To the best of our knowledge, no regulatory or legislative requirements need to be changed, and the economic and political cost to the EPA and industry would be slight.

INCENTIVE 8. ADVERTISE SAFETY ON PRODUCT LABEL*

A. PROBLEMS ADDRESSED

Pesticide labels display a large amount of information. For example, the user may get some idea of the safety of a product by determining whether it is registered for restricted or general use. In addition, pesticide products are put into toxicity categories based on human hazard. Category I pesticides, the most toxic, bear the signal word "Danger," the word "Poison" and a skull and crossbones on their label. Category II pesticides are somewhat less hazardous and are designated with the word "Warning." Both Category III and the least toxic Category IV pesticides must bear the signal word "Caution." Various other warnings and precautionary statements also provide some clues as to a product's safety. For example, all pesticide product labels must include the statement "Keep out of reach of children." Precautionary statements also warn the user about danger to humans, domestic animals, beneficial organisms, and other non-target organisms.

Although Catetory I pesticides are well identified, the user may be confused in determining the relative safety of products in other categories, especially Category III and Category IV products which bear the same signal word. The aim of this incentive is to eliminate this problem by some minor changes on Category III and Category IV pesticide labels.

B. BACKGROUND

No previous attempts have been made to specifically address this problem. Before the Section 3 Guidelines were published, it was suggested that no signal word would appear on the label of Category IV pesticides. However, this was not done because of the belief by some parties at EPA that all pesticides are hazardous and should bear a warning.

Pesticide companies can petition EPA for the removal of the child hazard warning from a specific pesticide label. However, the exact criteria used in making these determinations are somewhat vague. The requirement will be waived if the "likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children."** It does not appear that the child hazard warning has been removed solely on the basis of toxicity.

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*Based in part on preliminary incentive 61 (Safety Index).

**Federal Register 40(129):28279.

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Originally, the idea of a "safety index" was suggested. This index would rate pesticides according to their hazards in humans, and this numerical value would appear on the label. The idea has since been revised, because of the overwhelming problems in designing such an index and educating the user to understand it.

C. SPECIFIC INCENTIVES*

The specific goals of this incentive are to allow pesticide users and producers to distinguish between Category III and Category IV pesticides. In addition, the indirect goal of this incentive is to increase the use of safer products, and to allow the possibility of users creating a demand for the less hazardous products.

Two options are suggested:

- A pesticide company having a Category IV pesticide could petition to have the signal word removed from its label. Obviously, before implementing this procedure, EPA must establish criteria for the waiver of the signal word. The only requirement might be that the pesticide be in Category IV, although EPA could make the restrictions even narrower. In any case, the criteria should be specified in detail.
- A pesticide company having a Category IV could petition to have the statement, "This is a Category IV pesticide, the least hazardous category (to humans) registered by EPA" put on their label.

The most probable means of implementing either option is through a PEPS (Pesticide Enforcement Policy Statement). This vehicle has been used for somewhat similar problems in the past. In addition, product managers of Category IV pesticides could notify the respective registrants of the possibility of label changes, and would also be in charge of reviewing petitions.

In the evaluation of this incentive, the number of requests and the number of waivers of the signal word would be monitored. This procedure would be relatively simple, indicating the success or failure of this incentive in a short time. The long-term monitoring of the incentive would be much more difficult. The change in companys' directions or promotion of safer products could be monitored, but there would be no cause and effect relationship.

D. POSSIBLE RESULTS AND IMPACTS

If implemented, this incentive would provide a means for registrants to indicate by some slight label changes that their product is less hazardous to humans than are other products. The short-term impacts of these changes are not great. Since Category IV products represent approximately 5% of the total products, even if label changes were made on all of these products, the change would not be overwhelming. On the other hand, the incentive is simple in concept and would not require a great amount of effort. The existing agency mechanisms (PEPS) should be adequate for implementation, and the administrative burden of maintaining the incentive would be minimal. The greatest burden to EPA would be the establishment of criteria for the petitions.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

Although there are no burdens to the users as a result of this incentive, there are some costs to the registrant. Some may feel that the cost of label changes would not offset the possible benefits they would receive. In these cases, the effects of the incentive may not be seen so rapidly, since the registrants may wait until registration of the product to make the label changes.

Two parties could receive benefits from this incentive. The users would be provided with additional information for their own cost-benefit analyses. The registrants would be able to then present their products to the consumer more accurately.

The long-term effects of this incentive are difficult to assess because of the small changes made and the uncertainties as to the future regulatory environment. The reaction of the consumers could be so positive that it would create a pull in the marketplace towards these less hazardous products. The possibility of this happening is probably small, due to the small number of Category IV products at the present time. However, increasing environmental concerns may speed up this process. The purpose of this incentive, however, is not primarily to change trends in the development of products. The primary goal is simply to allow the consumer to determine which product is safer to use.

E. REQUIREMENTS FOR SUCCESS

In order for this incentive to be successful, three requirements must be met.

First, the incentive must be acceptable to and implemented by EPA. This is probably the most problematic step in the success of this incentive. Although these label changes seem to be consistent with EPA's goal of increased safety of pest control agents, there is some resistance to these types of changes. As mentioned previously, the removal of the signal word from the label of Category IV pesticides has been suggested and rejected. However, the removal as proposed here would be at the registrant's request and could be based on somewhat stricter requirements than those delineating Category IV. The statement identifying a Category IV pesticide should be acceptable to EPA. However, some EPA staff may feel that the statement implies that the product is absolutely safe. These label changes are, of necessity, a simplification of the problem; they are meant to address only human hazard, and do not consider hazards to wildlife and the environment. Hazards such as these may be considered in the development of criteria for the removal of the signal word.

Second, the incentive must be acceptable to and utilized by at least some portion of the pesticide industry. The probablility for some response is high, since similar measures were suggested by several companies during this program. Many companies objected to the idea of the safety index as mentioned above, because label changes would be necessary for all products. In addition, many felt that information presently on the label is sufficient. These companies, however, would be more favorable to this incentive which addresses only Category IV pesticides, and is not mandatory. Other companies (three out of seven commenting on this incentive) were in favor of a safety index, and thus, they would probably utilize this incentive.

Finally, the information provided by this incentive must be used by the consumer. Many of the comments from industry and EPA on the safety index suggested that extensive user education would be required. The proposed label changes are easy to understand and can be used immediately by the consumer in decisionmaking. The problem, however, is still whether they will use the information provided in determining which pesticide to buy.

The ultimate effect of this incentive will have on the decisionmaking of either the user or the producer is difficult to assess. In some cases, the consumer will have no alternative for the specific use concerned. In other cases, the choice may be between two products, one of which is less effective or more expensive than the other. Any indication of safety would probably not be used in these instances. However, safety might be a factor in situations in which two or more pesticides, similar in effectiveness and cost, are available for one use. In addition, safety is apt to be a prime factor in the home and garden market, where it might be considered above cost and efficacy. It seems that this incentive will aid some users, with the possibility of the numbers of users growing. The question also arises as to whether the magnitude of the impact will affect the pesticide industry in their pursuance of safe products.

The time required for the implementation of this incentive is not great or critical. The development of criteria and the issuance of the policy statement would probably take about one year. The first requests probably would be received within 1 1/2 years. After these initial steps, the incentive can continue indefinitely. There is the possibility of unpredictable events, such as changes in EPA policy regarding labeling and toxicity, which may affect this incentive. Barring such changes, this incentive should be effective for many years.

F. SUMMARY OUTLOOK

The outlook for this incentive is good. It should be acceptable to most parties involved and is not highly controversial. It is relatively simple and inexpensive to implement and maintain. Most important, however, it serves the needs of all parties concerned, EPA, industry, and users.

INCENTIVE 9. REDUCE THE RISK OF PRODUCT DEVELOPMENT BY INDUSTRY*

A. PROBLEMS ADDRESSED

The history of pesticide innovation, research and development, and the current trends in federal support of research and development suggest that private industry must continue to provide the basis and impetus for the development and use of new pest control products. Industry asserts that major impediments to the conduct of necessary research and development are the risks and uncertainties in the entire process of pesticide development, production, use, and regulation including:

- Uncertainty in the goals, objectives, operational policies, and attitudes of the regulatory agencies.
- Uncertainty in the future regulatory status of specific pesticides and/or pesticides in general.
- Lack of a stable benchmark system to evaluate the acceptability of pesticides with regard to safety and environmental concerns.
- Lack of a definitive policy of carcinogenesis, workable among industry, regulatory agencies, and the public.
- Risk of unknown health and environmental consequences of pesticides and their attendant liabilities.
- Risk of conducting unnecessary or unproductive research and development activities, caused, in part, by requirements of regulatory agencies.

These factors are interdependent. Collectively, they reduce the incentive for expanded, or in some cases even continued, research and development activities on pest control methods. Companies which have traditionally been leaders in pesticide development face increasing costs of research and development activities, greater uncertainty in the magnitude and probability of potential profits, longer payback periods, and lower internal rates of return, although they may experience less competition. As a result, corporate planners and financial investors may seek other activities for their available capital investment funds.

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*Based upon preliminary incentive 35 (Definitions of Standards for Safety) and suggestions by industry and government representatives during review of "Interim Working Document."

Just as some risks and uncertainties are increasing, the increasing demands for pesticide products for cost-effective agricultural production, structural, right-of-way, public health, and home and garden use result in a potential for higher profits and larger markets. Individual companies must base continued R&D investments on their own assessment of the risks and uncertainties of the business and the potential returns on these investments. The current trends are interpreted by industry as increasing risks and uncertainties in pesticide development, reducing the return on R&D investments, resulting ultimately in increased costs of pest control and/or decreased availability of pest control methods.

The purpose of this incentive is to help reduce some of the uncertainties over which the federal government exercises control, and thus to help establish a climate in which industry-funded pesticide research and development over the long term can have more certain returns.

B. BACKGROUND

The data that support the problems indicated above are widespread in the trade literature, presented at various industrial meetings, reported in testimony before the House of Representatives and Senate, agricultural and environmental committees, and provided in response and comments to regulations and guidelines proposed by the Office of Pesticide Programs. Appendix B of this report presents both qualitative and quantitative data and impressions gathered from discussions with industry and government representatives on these problems; this information will not be repeated here. Whether those problems are real or only perceived by industry and the public is of secondary importance if the result will be the lack of continued pesticide R&D efforts.

Since the passage of FIFRA, as amended, OPP has proceeded to implement the law and its accompanying regulations. In the process, OPP has already addressed some of these problems and explored several approaches to their long-term solution.

A pesticide strategy document was prepared in May 1974 which presented EPA's policies and operational plans for implementing the new legislation. Much of the law has now been implemented, but new regulations and procedures are still being developed. EPA has issued a second draft pesticide strategy document, which considers the regulatory issues to be addressed in the next five years. Through careful consideration of these issues and the approaches which EPA plans to take, industry and other participants in the pesticide development process should have a better overview of the regulatory environment and may be able to guide their work accordingly. However, a five-year regulatory planning horizon is short compared with the time for pesticide development or with the active and profitable lifetime of a pesticide product. Thus pesticide developers still face considerable uncertainty in their current research and development efforts. Furthermore, both industry and government recognize that even the best planned strategy cannot be expected to remain unchanged in view of recent and anticipated developments of the environmental and safety effects of chemicals.

The uncertainty in the registration process and its impact on new product R&D has been a major concern of industry. EPA has attempted to reduce this uncertainty by involving various affected parties in the development of registration requirements and guidelines, by publishing detailed registration guidelines, and by adopting an open information policy. Despite these efforts, registration and reregistration procedures are still changing, and industry is skeptical of their long-term stability. (See Incentive 3.)

The attitudes and relationships between the regulator and the regulated have been fluctuating. During the period from 1960 to the present, these relationships have changed from exchanges of scientific and technical information, with an active policy toward pesticide registration to litigation and adversary proceedings with an effort (perceived by some parties) to delay or prevent pesticide registration. Heated interchanges, emotional statements, less than impartial attitudes, and mutual distrust have been accorded to both the government and industry.

Several attempts have been made by the government and by industry to resolve or change some of the attitudinal problems. Open meetings have been held, policy and procedures for registration and information exchange have been changed, independent scientists and experts have been used, the product manager concept has been introduced, and other actions taken to reduce conflicts between the parties. Nevertheless there is a belief by some government staff members that industry actively and subversively attempts to circumvent, ignore, or cloud the regulatory issues. Similarly, the attitude of some industry members is that the government proceeds beyond its legal ground of regulation. Although these attitudes are common in the process of federal regulation of industry, additional efforts might well be expended to improve industry/government relationships.

The current policy and attitudes of OPP towards safety, particularly that related to carcinogenicity of pesticide products, lead to uncertainty in pesticide R&D decisions. Considerable controversy exists over carcinogenicity versus oncogenicity, threshold values for chemicals in the environment, tolerances on food products with respect to dietary intake, and the general question of "how safe is safe." The basic questions that need to be resolved must address all chemicals in the environment and not pesticides alone. Because a broad federal policy on carcinogenicity and safety does not exist, and probably will not for several years, OPP has had to make its own interpretations of environmental and human safety. Industry questions whether the current policy is too strict; others question whether the policy is too lax. As more data are accumulated and as our understanding of carcinogenicity increases, the regulatory agencies and industry must collectively and constructively work on such a safety policy using the best available information.

Another area in which considerable controversy exists is the use of risk-benefit analysis or cost-benefit analysis in the process of pesticide registration. Industry believes that insufficient attention has been paid to the benefits portion in cost-benefit analysis as compared with the environmental and safety costs. Although these factors are considered explicitly in the processes of cancellation and rebuttable presumption against registration, other regulatory decisions may benefit from a broader consideration of costs of pesticide use versus benefits. EPA has sponsored work in this area to develop methodologies and approaches to use the cost-benefit analysis. Further, programs such as the Substitute Chemicals Program have been initiated to obtain and review data on costs and benefits of pesticides that may be used as substitutes for others. Such efforts can be expanded both for public information and benefit.

This discussion suggests that OPP has made considerable progress in addressing some of the risks and uncertainties perceived by pesticide developers. Continued and expanded efforts could have long-term impact by ensuring a healthy viable industry capable and willing to make R&D commitments that result in new products to meet market and regulatory needs.

C. SPECIFIC INCENTIVES*

The specific long-term goal of this incentive is to reduce the risks and uncertainties of industry-funded pesticide research and development. The incentive focuses on actions the federal government can take to reduce risks in the development process, without direct involvement in the R&D process itself. Further, the incentive is directed at actions other than those related to registration of pesticides, addressing the creation of a working environment in which industry will continue to be willing to invest R&D funds in the development of new products that can meet corporate goals of profitability and return on investment and can meet user needs for specific pesticide products.

The incentive has several action areas:

- Develop, publish and implement a long-term (ten-year) pesticide regulation plan, i.e., a strategy in the broadest sense. The plan should reflect a management strategy, i.e., methods for addressing pesticide-related issues and not specific operational strategies. Specific subjects in the plan should include:

  (1) Well-defined objectives and goals of Office of Pesticide Programs of EPA.

  (2) Statement of the current and anticipated future roles, relationships, and interactions among OPP, the EPA offices, other federal and state regulatory and operational agencies.

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*Portions of this incentive were modified and amplified as a result of the Conference on Developing Incentives for Pest Control Methods. The reader is urged to examine the Conference Report for a discussion of these changes.

(3) Procedures for interaction of OPP with industry and the public.

(4) Statement of the long-term approach to the control of adverse environmental economic and social effects of pesticides, including identification of critical issues and possible means toward their long-term resolution.

(5) Outline of the decisionmaking processes to be followed by OPP in the next ten-year period.

(6) Anticipated future regulatory changes and the probable sequence of those changes.

- Continue to create an environment of scientific and technical information exchange, effective communications, working relationships and attitudes between OPP and the pesticide industry. The attitudes developed must recognize the multiple goals and objectives of OPP, the regulatory role of EPA with relation to environmental and human safety, the need to foster the development and registration of safe and effective pest control products.

- Provide for effective and extensive private, public, and interagency participation in areas of pesticide regulation and decisionmaking. Possible actions may include:

(1) Formation of science courts to assist in regulatory decisionmaking.

(2) Use of inflationary, regulatory, or research impact statements.

(3) Formation of an effective federal interagency working group.

(4) Use of industry and university, as well as government, resources to provide the scientific basis for regulatory procedures.

(5) Develop an effective industry/government interchange program.

The goal of this effort is the most effective utilization of available resources and information applied to the solution of current pesticide problems, and not creation of an environment in which the regulatory process of pesticide development becomes dependent upon or dictated by selected interest groups.

- Develop a stable internal organization within OPP in terms of staff, organization, functions, and operations. The intent is to create an organization with internal stability, appropriate talent and expertise, and a structure which facilitates interaction with other agencies, the public and industry and a view of confidence from both the public and private sectors. Development of this organization may require additional funding, staffing, training, organizational development effort, but is not intended to be a need for total reorganization or restructuring.

(1) Pesticide Regulation Plan

The action proposed herein is to build upon recent efforts of OPP in developing its latest draft strategy and to develop a more comprehensive, longer term, pesticide regulation plan. The plan will be a benchmark for industry and public understanding of the future actions of EPA related to pesticides. It will serve as input and guidance for industry's research and development decisionmaking process. However, the plan must necessarily maintain sufficient flexibility to allow EPA to adapt or modify its policies and regulations in light of new data and information on the costs and benefits of pesticides or changes in direction provided by Congress and the courts.

OPP, through a working group with representation of Criteria and Evaluation, Technical Services, Registrations and Operations Divisions, OSPR, and the Office of the Associate Administrator, should develop a hierarchy of goals and objectives to be accomplished in the next ten-year period. Inputs should be obtained from the scientific community (perhaps represented by the National Academy of Sciences), the legislature, other federal agencies (e.g., USDA), the public, and industry. The goals and objectives would be the focus of the pesticide regulation plan and subject to public comment and review. Careful and explicit formulation of the goals and objectives could assist in a development of the remainder of the plan as well as provide a basis for long-term stability within the agency. Methods for measurement of agency performance and a timetable for meeting the goals and objectives should be specified.

The second part of the proposed pesticide regulation plan would be the delineation of the roles, relationships, contributions and interactions of the many agencies, organizations and groups that must cooperate to achieve OPP goals and objectives. Roles could include: legal, regulatory, enforcement, informational, support of research, advisory, training, etc. Relationships could be formal or informal, should indicate responsibility and authority, and should convey an organizational structure among those involved with pesticide regulation. Specific contributions expected from agencies or groups--e.g., research, development, information, data collection, legal services--should be defined. Finally, the nature and frequency of the interactions among the various parties should be spelled out. Present roles and relationships, as well as trends or anticipated changes in the next ten years, should be identified. Specific areas to be covered in this part of the plan would include:

- Establishment of roles, relationships, inputs of:

federal agencies:	EPA-OPP, ORD, OGC; USDA, Dept. of Interior, NSF, NIH, DOC
state agencies:	state agricultural environmental agencies, state universities

- Designation of responsibilities and authorities of APPAC (Administrator's Pesticide Policy Advisory Committee), SFFIAC (State Federal FIFRA Implementation Advisory Committee), and other formal or ad hoc committees.

- Differentiation between regulatory and support roles of these groups and agencies.

Clearly, this part of the pesticide regulation plan could not be accomplished by OPP, or even EPA, alone. It would require interagency and congressional cooperation and approval. The development effort would have to be consistent with the goals and objectives of the individual agencies and the current mandate of OPP to implement and administer FIFRA, as amended.

Equally as important as defining the government role and interaction in the pesticide regulation plan, is the definition of the roles, relationships and opportunities for public and industry participation. The pesticide regulation plan should define the types and levels of interaction of industry with OPP and other agencies (for example, as described in Incentive 7) the formal and informal contacts which are expected to occur and information channels to be followed, and the types of information, needed for effective pesticide regulation, that are expected to be provided by industry and the public. Specific actions to enhance public participation are discussed later in this incentive.

In developing the strategic plan, OPP should explain its long-term approach to the solutions of any environmental and economic problems anticipated from pesticide use. Key issues should be identified and long-term approaches to their resolution should be suggested.

Because of the length of the pesticide R&D process, it is essential that long-term planning be accomplished by both EPA and industry. For example, there is considerable uncertainty concerning the position EPA will take with regard to certain classes or types of pesticides. Recognition of this problem and the approach EPA intends to follow could point the direction for changes in industrial R&D. Recognizing that new information and technology are still developing rapidly, and that changes in our understanding of pesticide effects are inevitable, both industry and government can benefit from carefully developed and disseminated plans for regulating pesticide supply and use.

Since decisionmaking is a major function of OPP--e.g., preregistration, registration, re-registration, suspension, cancellation, civil and criminal penalties, hazard evaluation--the pesticide regulation plan should provide a clear description of current and proposed future decisionmaking approaches. Guidelines for pesticide registration, criteria for rebuttable presumption against registration, the signaling process for pesticide hazard evaluation all represent decisionmaking approaches OPP has been developing. A more comprehensive decisionmaking plan should be prepared, indicating the roles of the various divisions and offices within OPP, procedures for internal and external review, use of advisory groups or other agencies in the decisionmaking processes, and the internal OPP procedures. The time frame for developing and implementing these decisionmaking processes, and the expected timing (duration) of the decision processes, and the inputs required from various parties should be identified. The decisionmaking processes should be published in the Federal Register for comment from industry and other groups. Alternative processes should be sought and evaluated.

Although the pesticide regulation plan would be followed for a long period, new inputs, data, congressional mandates, and information will require regulatory and procedural changes. Thus, the regulatory plan should specifically address the processes that will be used to plan and make changes in regulations and procedures. Further, the plan should identify, wherever possible, those processes, regulations and procedures that will be most subject to change, and a time frame for the changes.

The long-term pesticide regulatory plan would require considerable effort in its development, would undoubtedly be criticized by various interest groups. Nevertheless, the plan would establish a baseline from which expectations of OPP's and other federal agencies' actions in pesticide development could be developed.

The pesticide regulatory plan should be revised as needed, following a thorough auditing of the implementation, effectiveness and timeliness of the plan in relation to OPP goals and objectives.

(2) Open and Effective Communications and Information Exchange

The Office of Pesticide Programs has announced its adoption of an "open information exchange" policy, which should foster communications between the regulating agency and regulated groups, primarily industry. This policy will be a major step in achieving a better relationship and more constructive attitudes between EPA and industry. There is still a need, however, for open and frank discussions and information exchange--and, in some instances, a need to restrict information exchange to assure confidentiality of proprietary data. Several specific steps that could be taken to foster attitudes of mutual confidence and understanding, yet not lead to relationships in conflict with an effective regulatory process, are described below.

- EPA/industry planning conferences. Each year, and in the formative steps of any new program by the OPP, a joint industry/EPA planning conference of several days duration should be held to: provide an overview of current plans, identify actions to be taken in the near term, request input from interested and informed parties, and provide a mechanism for communications in a non-adversary situation. Such conferences can encourage industry, university and public participation to help eliminate surprises which decrease positive agency/industry attitudes. EPA has held open discussions on regulatory matters in various parts of the country, and held briefings explaining new regulations or programs; these should be continued and implemented earlier in the planning process.

- EPA/industry/public technical workshops. A series of publicly attended, planned and coordinated workshops on technical and scientific issues relevant to pesticides should be sponsored by EPA and other federal agencies. These workshops would provide an awareness of current technical information to all parties in the regulatory process, aid in promoting the use of new techniques and approaches to pesticide research investigations, and provide practical information for use by regulatory officials. Sharing of non-proprietary information on pesticide research development and use would be the focus of the meetings.

- Early circulation/review of EPA policy/procedure information. The broad distribution to industry and the public of EPA information and documentation related to future guidelines, policies and procedures should be continued and expanded. Seeking constructive inputs can significantly enhance mutual attitudes of EPA and industry.

- Clear definitions of proprietary/restricted data and information. EPA, working with other federal agencies and industry, should clarify and resolve current issues surrounding the "3(c)(1)(D)" provision of FIFRA, as amended. Definitive procedures for identifying and handling "trade secrets," proprietary data, data for which compensation is appropriate, and public information in the context of FIFRA, as amended, and the Freedom of Information Act should be developed and implemented.

- Use of EPA regional staff in pesticide regulatory matters. Procedures and practices for communications and information exchange between industry, the public and EPA at the regional level should be established and their use encouraged. These would permit more effective utilization of resources within EPA, as well as ensure that problems and issues of local or regional significance are addressed. EPA has considered the possible decentralization of activities and suggested several approaches to utilize EPA regional pesticide staff in registration and other regulatory affairs such as enforcement, emergency exemptions, abatement and control, etc. These suggestions should be examined in more detail to establish that they can aid in the solution of regulatory problems, rather than in creation of new ones. Interagency interaction on pesticide issues at the regional level is a second level of communication and information exchange that needs to be fostered.

- Continued development of the industry/government interchange program. An important contribution to exchange of information among industry, universities and government can occur through strengthening of a broad-based program to exchange staff among the various parties for specific purposes and/or time periods. Federal internships or industry-sponsored fellowships are several approaches which should be tried more extensively. New knowledge can be transferred, attitudes improved, and avenues opened for a better working environment.

These steps require careful consideration and deliberate implementation in order to be effective.

(3) Public Participation in the Regulatory Process

A third action step involves increased public (including industry, academia, and public interest groups) participation in the pesticide regulatory process. It may be argued that more public participation does not reduce the risks and uncertainties in the pesticide research and development process. Further, many of the processes for public participation are expected to lead to delays in the regulatory process, and that uncertainty is compounded by any lengthening or increasing of its complexity. However, another view is that the public ultimately creates the demand for and uses pest control products; hence, the public should equally play a role in ensuring an effective regulatory process consistent with its interests.

The current process of publication of regulations and guidelines in the Federal Register with opportunity for comment, public hearings and adversary procedures dealing with suspension and cancellation can be expanded by several means described below.

These action steps, and OPP's continued efforts to utilize a broad range of government, university, industry, and independent resources to aid in its policy- and decisionmaking can lead to a climate in which informed and trusted interaction is the rule rather than the exception. Caution must be exercised to ensure that the outputs of the processes can be utilized effectively, and that additional problems are not precipitated because of the added public and private interaction.

- Environmental/inflation impact statements. For each major new regulatory approach or program to be implemented by OPP, an environmental/inflation impact statement should be prepared with opportunities for participation and comment by industry, public and other interest groups. EPA's current policy is to prepare (voluntarily) Environmental Impact Statements for its most significant regulatory actions.* EPA normally will prepare an EIS for (1) cancellation of pesticide registration after an adjudicatory hearing under Section 6(b) of FIFRA, as amended, and (2) pesticide disposal regulations under Section 19 of FIFRA, as amended. This policy should be extended to cover other major actions such as significant changes in registration requirements, policies developed for 3(c)(1)(D), etc. The purpose of this impact statement will be to ensure that both the benefits and the costs of proposed regulatory actions are clearly evaluated prior to the implementation of these actions. Although such impact statements might best be prepared by a federal agency apart from the regulating agency; it is difficult to suggest an agency other than EPA. Representatives of the parties impacted should assist in the preparation of the impact statement, not only in its review. Subjects covered by the impact statement should include: the parties affected--both near and long term, direct and secondary costs of the program and its implementation, benefits to various parties, alternative approaches, and other topics consistent with EPA and NEPA guidelines.

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* Federal Register, Vol. 39, No. 204, October 21, 1974.

Inflation impact statements are also currently required for the promulgation of regulations or rules by any executive branch agency. Criteria for identification of rules for which such statements must be prepared have been developed by the Office of Management and Budget.* EPA's criteria are: impacts must be $100 million annualized incremental cost (at the production level) or a 5% greater increase in the price of any "major" product. Consideration should be given to lowering the minimum required criteria for inflation impact statements or collecting certain actions, with a statement prepared for several.

- Research impact statement. Suggested by Djerassi,** a research impact statement should be incorporated into the inflationary impact statement or prepared independently for new regulations or procedures required by EPA which cause substantial additional research and development efforts by participants in the pesticide R&D process. One of the purposes would be to explore fully the impacts of the regulations on the parties which must conduct the research effort. EPA should play a major role in preparation of such impact statements but opportunities for participation and comments should be available to those who will participate in the research, be affected by its results, or bear the cost burden. Again, such statements must be prepared on a timely basis and not result in undue delays in the regulatory process.

- Cost-benefit analysis. Cost-benefit analyses are being conducted by EPA as part of the procedure for cancellation of pesticide registration and as part of the rebuttable presumption against registration process. Cost-benefit analyses should also be considered for other portions of the OPP regulatory process where such analyses would aid in the decisionmaking process. For example, they may be a part of the research or inflationary impact statement or part of emergency or local use requirements. They must be conducted independently as part of additional requirements for registration of selected pesticides. Cost-benefit analyses should not be required for every pesticide registration, nor should they be used to discriminate among several pesticides proposed for the same use. They should be carefully considered for pest control measures that have possible adverse environmental effects, as defined by criteria developed and specified by OPP and reviewed by others. One purpose of the cost-benefit analysis would be to allow OPP to recognize when not to cancel a pesticide due to hazard considerations. The results of cost-benefit analysis will make the cost and benefits better known to the concerned and informed public so that a greater understanding of the decisionmaking can occur.

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* Executive Order 11821, Federal Register, Vol. 39, No. 231, November 29, 1974.

** Djerassi, C., Christina Shih-Coleman, John Diekman, "Insect Control of the Future: Operational and Policy Aspects," Science, Vol. 186, p. 596.

Cost-benefit analysis must be placed in perspective. Not all actions of OPP should be subject to cost-benefit analysis. Reasonable alternative actions must exist for such analyses to be useful. For many of OPP actions, risks and hazards will undoubtedly be examined first, and for those areas where there are high risks or hazards, cost-benefit analysis should be conducted.

- Science court/board. Proposed by Kantrowitz,* the use of a science court (or board) for assistance in policy and regulatory decisions by OPP should be explored. Both industry and government prefer that scientific and technical questions be judged by those trained in appropriate disciplines and not be resolved only on legal considerations. Thus, a science court might be used when scientific or technical data are limited and scientific judgment is needed to clarify issues. Conversely, where social values and non-technical criteria are in question, a court (or board) of scientists will probably be no better (or worse) than another concerned and informed group in aiding regulatory decisions. The science court does not obviate the adversary procedures now encountered in OPP decisions, but places responsibility for some of the decisions with those who are well qualified to debate and judge the scientific merits of the individual cases.

- Formation of a new interagency pesticide working group. The Federal Working Group on Pest Management functioned primarily in an advisory or information role and has been disbanded. There is the need for a new Interagency Pesticide Working Group that is concerned with, interested in and active in pesticide management. The working group should be reevaluated and given a new structure, organization and mission to provide specific data, information and assistance in the pesticide regulatory process. Specific goals, objectives and assignments (for example, formulation, review, and coordination of research programs in specific areas such as biodegradation, pesticide disposal, monitoring)--with appropriate responsibility--should be given to the group and its committees. This can broaden federal participation in the entire pesticide regulatory process.

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* Science, Vol. 192, p. 129, July 9, 1976.

(4) Internal Organizational Stability

In planning for its future role in the regulation of pesticides, OPP should build, strengthen, and stabilize its staff and organization. Although some organizational changes will be demanded by new programs and priorities, and although staff will change as a result of new hires, terminations, retirements, etc., a well-conceived organization and personnel management plan will enhance OPP's relationship with other federal agencies and with industry. A first step might be an audit of the current organization, responsibilities, skills and staff. The objectives, requirements and any deficiencies of internal administration, communication and work performance channels would be delineated. This information, combined with clear presentations of the goals and objectives of OPP, should set the stage for staff and skill additions or consolidations, establishment of work centers or program offices, or organizational development activities.

This does not suggest a reorganization or restructuring of the agency. It provides for an organizational plan which will help OPP meet its obligations under the law and will help keep a skilled and dedicated staff interested in the most effective long-term resolution of pesticide-related problems. Specific steps such as upgrading salary levels of registration staff and adding necessary support allocations, have already been mentioned in other incentives. Such a staff and organizational development program could enhance the image of OPP with both industry and the public and help create, in both perception and function, a stable and effective organization.

D. POSSIBLE RESULTS AND IMPACTS

The incentives listed above represent a collection of actions that EPA should consider for deliberate implementation over the long term. Several actions are independent of the others both in concept and in timing; others can be most effective when coordinated with others.

If successfully implemented, the actions could lead to a more effective working relationship between industry and government agencies responsible for pesticide regulation, and to the establishment of an economic and regulatory climate in which industry will seek to invest in research and development of new pest control products. The incentives could lead, over the long term, to achievement of EPA goals of removing some of the obstacles or hinderances to pesticide development caused by regulation. They could lead to a more direct control of pesticide policy by the public, informed of current issues, and capable of weighing the costs and benefits of pecticide use and regulation. It is possible that they would ultimately lead to the industrial development of biologically integrated pest control approaches, but this could be an indirect result of the incentive actions.

Although the ultimate objectives of this incentive are long-term, short-term benefits and costs should be observable and measurable. The development, publication, and initial implementation of a long-term pesticide regulation plan could be accomplished within one year. It could serve to clarify OPP objectives and goals, set the stage for future actions, and permit EPA to take a more definite position on major issues. The development of an effective operational strategy and plan would follow and require additional time and effort. A measurable result could be establishment of interagency agreements specifying federal and state agency roles and interactions within a two-year time frame. Interagency conflicts could decrease and coordinated cooperative efforts could increase. Another measure of implementation of the incentive could be the establishment and use of methods for improved OPP/industry interaction, increases in productive working conferences, open meetings, planned workshops, etc. The content of these interactions, as well as the participants' attitudes, could show changes in the first few years.

A measurable result of the identification of critical issues and planned approaches to resolve these issues, could be a perceptible decrease in the number of crisis situations within EPA. The number of major regulatory changes and the frequency of occurrence could decrease within several years.

Within several years the attitudes of the various parties involved in pesticide regulation could change from the present tendency of distrust, polarization, and uncooperativeness to one of mutual understanding and reasonableness. This could be evidenced by changes in public statements of industry and government representatives, fewer complaints to Congress, fewer lawsuits and adversary hearings, and fewer comments on proposed regulations or OPP programs. Effective use of inflation, regulatory, or research impact statements could lead to a better understanding of the consequences of OPP programs and a smaller financial impact on industry. Use of science boards, and diverse scientific bases for regulation could result in fewer contested decisions in regulatory affairs. Other impacts, such as internal OPP stability could be observable by the public, Congress, and industry within several years.

Indirect, but broad and long-term, measures of the success of implementing the incentive could be increases in the proportion of industrial R&D devoted to new product development and corresponding decreases in defensive and regulatory R&D, and decreases in the numbers of penalties, fines, suspensions, and cancellations issued by EPA.

Clearly some costs are associated with implementation of these incentives. Increased public and industry participation in the regulatory process, changes in agency staffing or required interactions, industry/government interchange programs, strategy and planning by OPP will require additional funds. Countering these increases could be the decrease in funds spent on unproductive research, lengthy adversary proceeding, industry/government regulatory confrontations, etc.

The costs of implementation of this incentive would be more in the commitment of human resources than in dollar spending. Government and industry staff are already devoting their efforts to pesticide regulatory problems; rechanneling of some of these efforts may be the major change required.

E. REQUIREMENTS FOR SUCCESS

A principal requirement for success of this incentive is the desire, commitment, and determination on the part of government and industry managers to participate in a rational and reasonable program of balancing the benefits and costs of pesticide use. A sustained effort that recognizes the probability of short-term set-backs, the difficulties of meeting the needs of diverse interest groups, the requirements for compromise, and the need for perserverance and patience of all parties is essential.

F. SUMMARY OUTLOOK

The outlook for the successful implementation of these incentive actions is mixed. Idealistically, many parts of the incentive could be successfully implemented in several years. Pessimistically, the current conflicts and diversity of interests would not permit resolution of important issues, changes in attitudes and significant reduction in the risk of pesticide development. Realistically, a few of the proposed incentive actions could be accomplished successfully through dedicated government, industry, and public efforts.

In any case, this incentive should be initiated and its development continued, in spite of any short-term set-backs and difficulties encountered.

TECHNICAL REPORT DATA

(Please read Instructions on the reverse before completing)

1. REPORT NO. EPA-540/9/77/008	2.	3. RECIPIENT'S ACCESSION NO.
4. TITLE AND SUBTITLE INCENTIVES FOR RESEARCH AND DEVELOPMENT IN PEST CONTROL VOLUME I		5. REPORT DATE DECEMBER 1976 6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S) WECHSLER, HARRISON, BURG, GIBBONS, PERWAK, TERRY.,		8. PERFORMING ORGANIZATION REPORT NO. 78167
9. PERFORMING ORGANIZATION NAME AND ADDRESS Arthur D. Little, Inc. Cambridge, Massachusetts 02140		10. PROGRAM ELEMENT NO. 11. CONTRACT/GRANT NO. 68-01-3133
12. SPONSORING AGENCY NAME AND ADDRESS Office of Pesticide Programs Strategic Studies Unit U.S. Environmental Protection Agency Washington, D.C. 20460		13. TYPE OF REPORT AND PERIOD COVERED Final 14. SPONSORING AGENCY CODE EPA/500/01

15. SUPPLEMENTARY NOTES

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16. ABSTRACT

This program identified, developed, and evaluated incentives (externally applied influences) that the federal government can offer to reduce barriers to innovation and thereby encourage the continued development of pest control methods by industry. The history of pest control innovation was analyze, and influences on current decision-making concerning industrial pesticide R&D were studied to provide background for the development of incentives. Then, 64 preliminary incentive ideas were devised and evaluated in accordance with a conceptual framework. These incentives were screened and ranked according to their feasibility, the acceptance by parties involved in their implementation, and their potential contribution to realizing the objectives of this program. Nine particularly promising incentive areas were developed further and evaluated in several possible future scenarios. Recommended incentives included specific actions designed to decrease regulatory hindrances to R&D, reduce the risk of product development by industry, increase the availability of minor use pesticides, lengthen patent life, advertise safety on the product label, increase utilization of Integrated Pest Management, and increase information and training for pesticide users. The insights and comments of representatives of the pesticide industry and government staff concerned with pesticide development and regulation were sought at several stages in the development of incentives.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Regulation Environment Pesticides Research Patents Toxicology	Crop groupings Minor Use pesticides Integrated pest management Regulatory hindrances Alternative futures Enterpreneurial risk Product testing Information and training Product labeling R&D incentives	06/F 06/J 14/F 05/C 07/A 02/B

18. DISTRIBUTION STATEMENT Release unlimited	19. SECURITY CLASS *(This Report)* Unclassified	21. NO. OF PAGES
	20. SECURITY CLASS *(This page)* Unclassified	22. PRICE

EPA Form 2220-1 (9-73)